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SCREW FIXATION OF IMPLANTS TO THE SPINE

by

PURVI SHANTILAL PATEL

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ABSTRACT

Bone screws are used to fix various implants to the human spine. Screw fixation can be difficult in osteoporotic bone because of its reduced strength. This research aimed to investigate screw fixation techniques in the spine. A questionnaire study, representing British and Irish spine surgeons, confirmed the potential for a simple screw positioning device and identified the need for an improved screw for osteoporotic bone. Determination of the compressive mechanical properties of 0.32 g.cm^{-3} , 0.16 g.cm^{-3} and 0.09 g.cm^{-3} polyurethane foam enabled them to be used as models for normal, osteoporotic and very low density osteoporotic, human cancellous bone, respectively. The screw pullout force from these bone models decreased with polyurethane foam density, implying that the quality of bone principally influences the strength of screw fixation. The angle of screw insertion and thread design was also found to affect screw pullout force, but not a small amount of screw toggling prior to axial pullout. No benefits in pullout strength were found when placing screws at 40° in a normal bone model or when using closely placed multiple screws in an osteoporotic bone model.

In loving memory of my

Devimaa, Nathubapa,

Dahyadada & Kashiba

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1. INTRODUCTION

Fracture and deformity of the human spine, from conditions such as tumours, trauma and abnormal spinal curvature, often requires hard stabilisation of the spine (Crawford and Esses, 1994). To achieve spinal stability, various rods, plates or cages are fixed to the vertebrae using bone screws (Vaccaro and Garfin, 1995). Screw fixation of these spinal implants is of great importance to the clinical success of the overall device. In spinal applications, the load that implants experience can be high and therefore it is important to ensure that the implant is properly secured to the vertebrae. However, due to osteoporosis this is not always possible, as this condition degrades the quality of bone available for screw fixation (Hu, 1997). Often termed the “silent” disease, the chronic nature of osteoporosis means that clinical intervention occurs late in the process, usually following an unexpected fracture (National Osteoporosis Society, 2006). Thus, preventative measures can be difficult to administer in osteoporotic (OP) patients. The incidence of osteoporosis is escalating; the population is living longer (Gjonça *et al.*, 2005) and those aged 50 or 60 years old are not considered old anymore. So there is likely to be a growing expectation among these patients, in their middle ages, to maintain an active lifestyle with minimal disability. Treatment options dealing with strengthening the bone in OP patients do exist, but the insertion of hardware using bone screws is often the last resort to restore some stability to the spine. However, internal constructs in the OP spine have been reported to fail due to screw loosening and loss of fixation at the screw-bone interface (Halvorson *et al.*, 1994; Okuyama *et al.*, 1993; Soshi *et al.*, 1991; Wittenberg *et al.*, 1991).

To address this issue, several published studies have considered the augmentation of screws with bone cement or hooks, to improve the strength of screw fixation (Becker *et al.*, 2008; Burval *et al.*, 2007; Chang *et al.*, 2008; Lotz *et al.*, 1997; Moore *et al.*, 1997; Tan *et al.*, 2004). There have also been reports on specially designed screws for OP bone (Becker *et al.*, 2008; Chen *et al.*, 2009; Cook *et al.*, 2001; Takigawa *et al.*, 2007). However, there are no valid test materials to model OP bone, which would be useful when designing screws for the OP spine. There is also a lack of literature on the various screw parameters, such as the effect of screw insertion angle, to enhance screw fixation in OP bone. In addition, the behaviour of a screw in the OP spine is not yet clearly understood.

The aim of this thesis was to investigate screw fixation techniques in the spine, particularly with regard to OP bone. The specific objectives were to:

- examine the current practice of screw surgery in the spine.
- determine a valid test material to model OP bone.
- use suitable bone models to investigate a number of factors that may affect the strength of screw fixation.

Chapter 2 presents the background information required to understand this thesis. Starting with a description of the anatomical terms used for the spine, the chapter continues by describing spinal implants requiring bone screws and their use in the OP spine. The chapter ends with some information on the mechanical testing of screws and discusses the advantages of using a bone model, which is relevant for the experimental work in Chapters 4-8. After

Chapter 2, all of the subsequent chapters include individual background literature, pertinent to that specific study.

Considered as a practice review, Chapter 3 presents the results of a questionnaire study undertaken to investigate a particular spine screw (pedicle screw) surgery, throughout the UK and Ireland. The chapter explains why such a study was carried out and includes the work of a preliminary survey, the results of which can be found in Appendix A. The opinions and experiences, of many British and Irish spine surgeons, on several topics in this thesis are presented and discussed in this chapter.

Chapter 4 marks the beginning of the experimental work described in this thesis; each experimental chapter is reasonably self-contained, with its own individual sections for the materials and methods, results and discussion. Chapter 4 presents work that has already been published (Patel *et al.*, 2008) and describes a study that was undertaken to characterise the mechanical properties of commercially available polyurethane (PU) foams as models for OP human cancellous bone; such foams can aid in the evaluation of bone screw performance, which is considered in Chapters 5-8.

In Chapter 5, the fixation of two types of bone screws in normal and OP bone models (defined in Chapter 4) are compared. The aim of the study was to determine how the pullout force of each bone screw is affected by the angle at which it is inserted. The findings are intended to determine the effect of screw insertion angles to achieve enhanced screw fixation in OP bone. The chapter provides a general discussion of the results followed by some analytical sections, based on theory published by other researchers.

Chapter 6 describes an experimental study that is related to a particular spine surgeon's idea; the surgeon's proposal for "screw" fixation without using a screw thread, but relying on an interference fit instead, is tested. The effect of pilot hole diameter on the pullout force of a dowel - modelled on a particular screw from Chapter 5, but without the screw thread - was investigated using the bone models defined in Chapter 4.

In Chapter 7, the screw pullout testing from Chapter 5 is taken a step further by performing screw toggling and subsequent axial screw pullout tests, in order to more closely approximate the physiological method of bone screw failure. The chapter describes work that has already been reported in the literature (Zindrick *et al.*, 1986), regarding *in-vivo* screw forces in the spine and biomechanical tests involving cyclically-loaded screws, and is followed by detailed sections on the materials and methods, results and discussion of the present study.

Chapter 8 is the last experimental chapter. It considers a clinical application of bone screws by testing spinal implants, i.e. STALIF TT™ fusion cages. A clear description of the STALIF TT™ cage is provided in Chapter 8. This chapter is intended to combine and complete the work from Chapters 5 and 7, by describing pullout tests of the STALIF TT™ cage from the bone models defined in Chapter 4.

Chapter 9 concludes this thesis by summarising and, where possible, linking together the results from Chapters 3-8. This chapter presents the overall conclusions with regard to the original aims of the research. Following Chapter 9 are Appendices A-G, which provides further information on a range of subjects; the reader is referred to the relevant appendix in

the text. Appendix H discusses the accuracy of the testing machines used in Chapters 4-8, whilst Appendix J contains the engineering drawings for the test rigs used in this thesis.

2. BACKGROUND

2.1 Chapter Overview

This chapter aims to provide the general information required to understand the following chapters. Sections 2.2 and 2.3 present the necessary anatomical terms that will be referred to in Chapter 3. Sections 2.4 and 2.5 introduce spinal implants requiring bone screws, which are investigated in the remainder of the thesis, and their use in the osteoporotic (OP) spine. Sections 2.6 and 2.7 provide some background information on the mechanical testing of screws and the advantages of using a bone model, which is relevant for the experimental work in Chapters 4-8. Specific background information on each specific part of the study is given in the relevant chapter.

2.2 Basic Anatomic Terminology

2.2.1 Planes of the Human Body

The human body has three principal reference planes (Middleditch and Oliver, 2005) that are mutually perpendicular (Figure 2.1). The sagittal plane vertically divides the body into left and right halves. The coronal plane divides the body into front and back halves. The transverse plane horizontally divides the body into upper and lower halves.

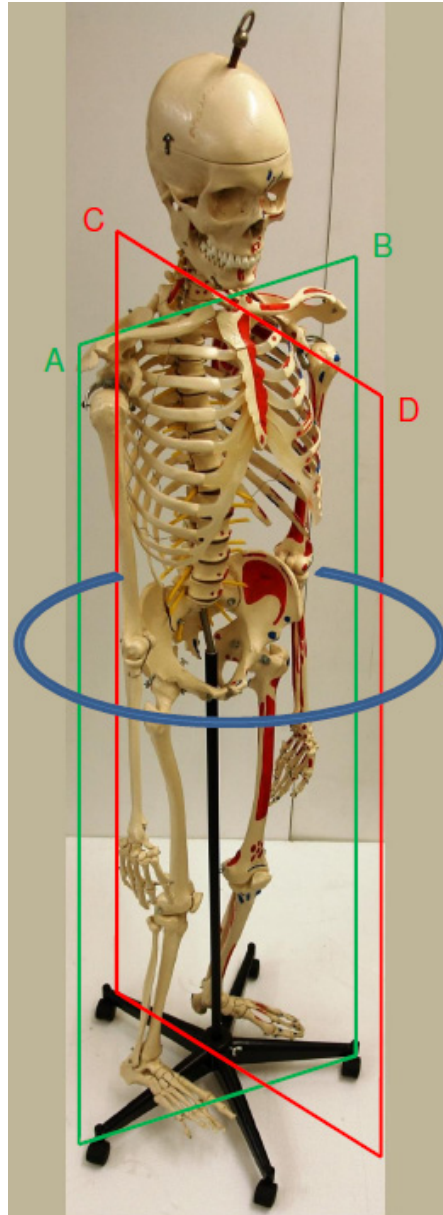


Figure 2.1 Planes of the body. AB, coronal (or frontal) plane; CD, sagittal (or median) plane; the blue circle encloses a transverse (or horizontal) plane.

2.2.2 Anatomic Directions

Surgeons often adopt a clinical vocabulary to efficiently communicate with each other. Figure 2.2 illustrates commonly used anatomic reference directions (Kurtz and Edidin, 2006). The upward direction is *superior*; the downward direction is *inferior*. The front of the body is referred to as the *anterior* part; the back of the body is the *posterior* part. The *lateral* direction points away from the middle of the body; the *medial* direction is towards the middle of the body. Regarding individual limbs, *proximal* refers to the area closest to the body; *distal* refers to the area furthest from the body. For the spine, *cranial*, or *cephalad*, is the direction towards the head, whilst *caudal* is the direction towards the lower end of the body.

Anatomic Reference Directions

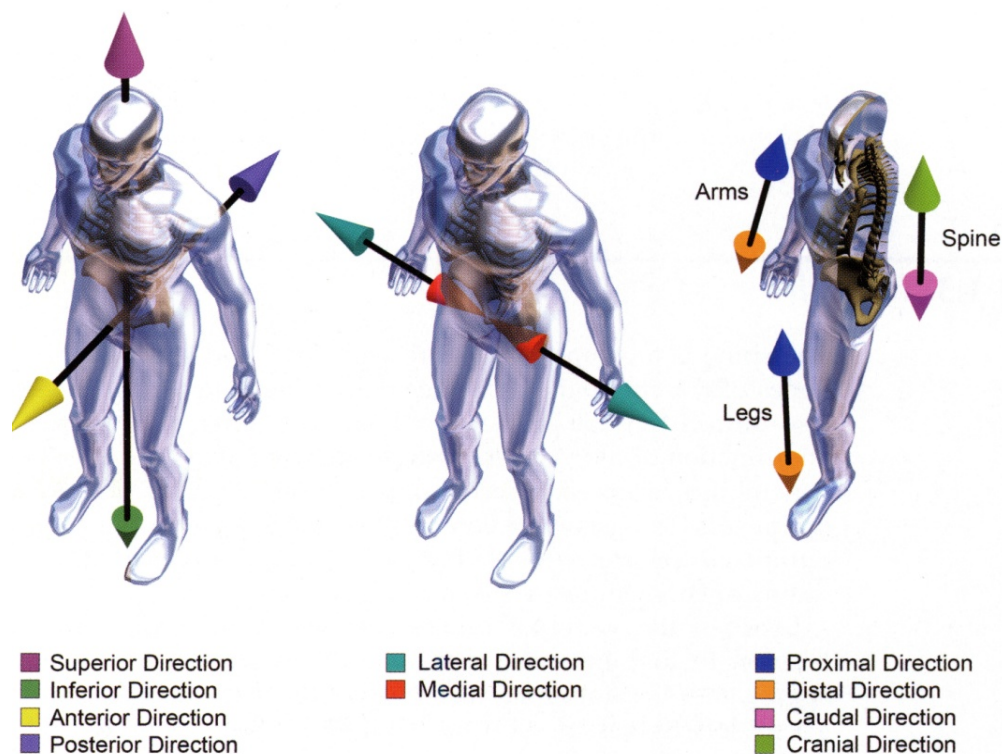


Figure 2.2 Anatomic reference directions (Kurtz and Edidin, 2006). *Reproduced with kind permission from Christopher Espinosa, Exponent Inc., and Elsevier Ltd.*

2.3 The Human Spine

2.3.1 Regions of the Spine

The human spine normally has 24 separate bony segments called vertebrae (Middleditch and Oliver, 2005). Progressing toward the caudal direction, each region of the spine is named as follows (Figure 2.3): *cervical* (C1-C7), *thoracic* (T1-T12), *lumbar* (L1-L5) and *sacrum* (S1-S5). The cervical, thoracic and lumbar regions normally consist of individual vertebrae. The sacrum, or sacral region, normally consists of a series of 5 fused vertebrae. Following the sacrum, another series of 4 fused vertebrae normally form the coccyx. Variations are common, especially for S1, which often exists as a separate vertebra, or L5, which is either completely or partially incorporated into the sacrum (Middleditch and Oliver, 2005).

Regions of the Spine

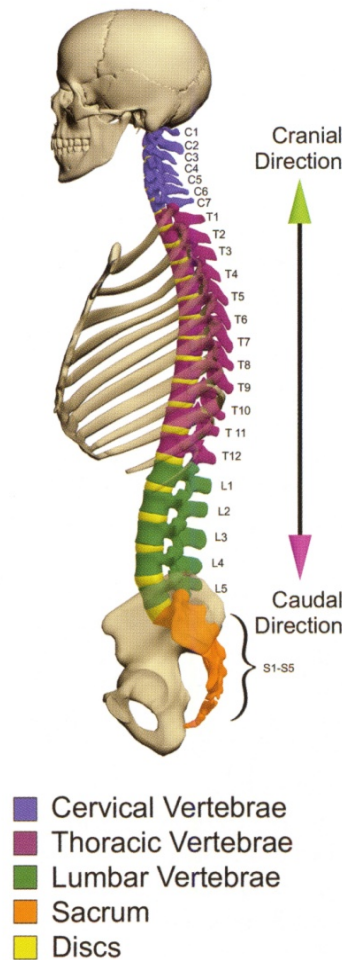


Figure 2.3 Cervical, thoracic, lumbar and sacral regions of the spine (Kurtz and Edidin, 2006). *Reproduced with kind permission from Christopher Espinosa, Exponent Inc., and Elsevier Ltd.*

Figure 2.3 typifies the normal curvature of the spine, when viewed from the side (the sagittal plane). A posterior view (the coronal plane) of the healthy spine usually appears to show it to be in a straight line; but when the spine is more like an “S” or a “C” shape, such abnormal lateral curvature is referred to as scoliosis (Kouwenhoven and Castelein, 2008). Scoliosis can cause rotation of the vertebrae and is typically classified as either congenital (caused by vertebral defects present at birth), idiopathic (cause unknown) or neuromuscular (having

developed as a secondary symptom of another condition, such as cerebral palsy or physical trauma) (Kurtz and Edidin, 2006).

2.3.2 Motions of the Spine

Figure 2.4 illustrates the motions of the spine (Kurtz and Edidin, 2006). The terms *flexion* and *extension* convey anterior and posterior bending respectively. *Lateral bending* occurs when the spine bends sideways away from the middle of the body. *Axial torsion* refers to rotation of the spine along its axis. Axial displacement of the spine, as a result of applying a tensile force, is termed *traction*. Compressive forces, from the muscles that actuate ligaments attached to the spinal column, can also cause axial displacement of the spine.

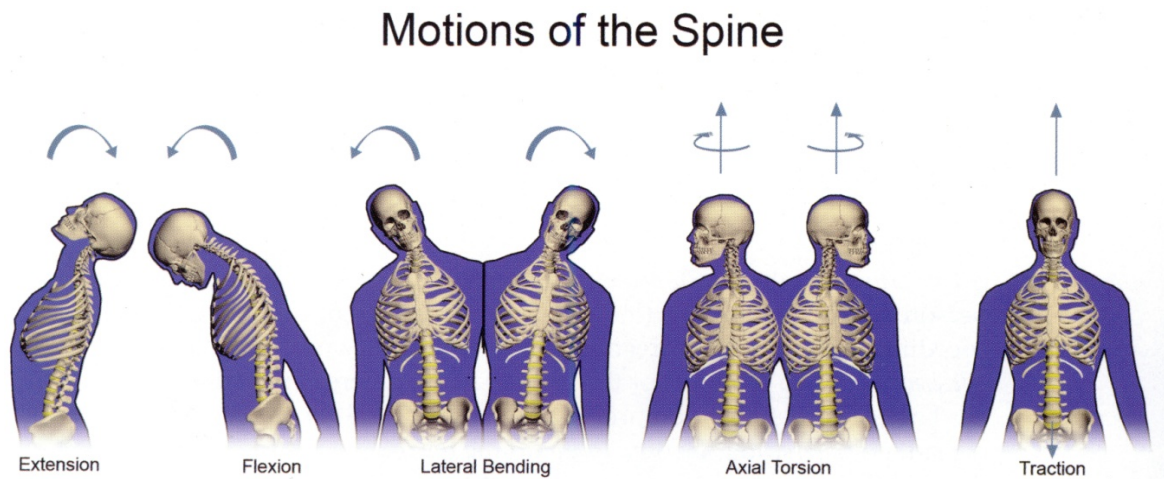


Figure 2.4 Anatomic terms used to describe the motions of the spine (Kurtz and Edidin, 2006). Reproduced with kind permission from Christopher Espinosa, Exponent Inc., and Elsevier Ltd.

The loads experienced by the spine are a complex combination of compression, shear, torsion and bending forces (Dolan and Adams, 1995). Most of the research into spinal loading has concentrated on the compressive forces acting on the spine, which arise from superincumbent body weight (approximately 55% of body weight, or 380 N for an average man) and muscle tension. During calm standing and sitting, the compressive force on the lumbar discs is approximately 500 N and 700 N respectively (Nachemson, 1981). However, only 380 N of this is due to body weight, so the remainder comes from the action of the posterior and abdominal muscles stabilising the upper body. During spinal flexion and when lifting objects from the ground, the posterior muscles must generate large extensor moments. Usually these posterior muscles operate on short lever arms about the ‘pivot point’ in the centre of the spinal discs (Figure 2.3), so the muscles must generate very high forces which then act to compress the spine (Dolan and Adams, 1995). During flexion and lifting, compressive forces due to muscle tension can rise to five to ten times superincumbent bodyweight (Dolan and Adams, 1993; McGill and Norman, 1987). The typical compressive forces acting on the lumbar spine when lying face upward, standing and sitting are 250 N, 500 N and 700 N respectively (Dolan and Adams, 1995). When holding a 5 kg weight in outstretched arms, the compressive force on the lumbar spine is 1900 N (Nachemson, 1981) and 5500 N when lifting a 30 kg weight from the ground (Dolan *et al.*, 1994; Potvin *et al.*, 1991).

2.3.3 Anatomy of the Individual Vertebra

Figure 2.5 illustrates the anatomy of a typical L3 vertebra (Middleditch and Oliver, 2005). Other vertebrae have the same basic components: an anterior *vertebral body* and the posterior elements that enclose the *vertebral canal* (through which the spinal cord or cauda equina run). The posterior elements, comprising the *laminae*, *spinous process*, *transverse processes* and the *articular processes*, serve as attachment sites for various spinal ligaments and muscles. The *pedicles* form a bony link between the vertebral body and posterior elements (Figure 2.6). The pedicles are of particular interest because this is where bone screws are placed during internal fixation of the spine, which is described in §2.4.

Zygapophysial, also called facet, joints are formed between the *superior articular process* of one vertebra and the *inferior articular process* of the vertebra above (Bogduk, 2005). Between two consecutive vertebral bodies lies an *intervertebral disc* (Figure 2.3), with the exception of the first and second cervical vertebrae and most sacral vertebrae (Middleditch and Oliver, 2005). When two vertebrae sandwich an intervertebral disc, the entire segment forms a functional spine unit or motion segment.

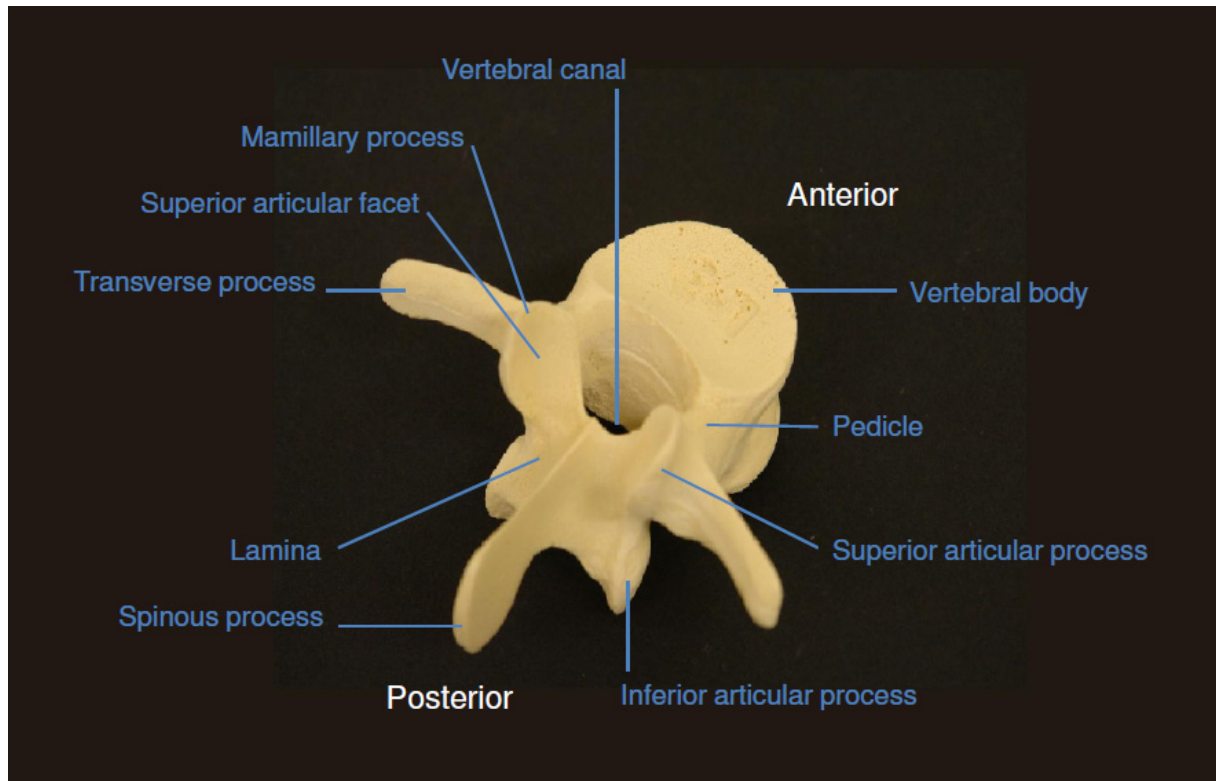


Figure 2.5 Anatomy of a typical L3 vertebra. Note that the *mamillary process* is the small rounded bone part on each *superior articular process* of a lumbar vertebra (Middleditch and Oliver, 2005).

Each vertebra has three functional components (Figure 2.6): the vertebral body, pedicles and posterior elements (Bogduk, 2005). The vertebral body is the major weight bearing component; it is designed to withstand axial compressive forces. It consists of a hard outer shell of cortical bone and a softer inner cancellous bone cavity. Cortical, or compact, bone is characterised by its densely packed layers of bone. Cancellous, or trabecular, bone is characterised by its porous matrix. The cancellous bone structure of the vertebral body extends into the posterior elements, via the pedicle (Bogduk, 2005).

The role of the pedicles is to transmit tension and bending forces between the posterior elements and the vertebral body. They can be likened to thick-walled cylinders that resist bending in any direction, through a combination of tension and compression along opposite walls. The pedicle is often considered to be hollow, with a surrounding thick wall of cortical bone (Bogduk, 2005). However, bundles of trabeculae (bony struts) do sweep out of the vertebral body, through the pedicles, and into the posterior elements; these trabeculae are arranged horizontally and obliquely within the pedicles (Middleditch and Oliver, 2005). A thick pedicle wall, made from cortical bone, protects this inner matrix of trabeculae (cancellous bone). The amount of cancellous bone and its significance within the pedicles has been a topic of debate amongst surgeons (Mr A. Jackowski, personal communication); this is discussed further in Chapter 6.

The posterior elements are designed to protect the spinal cord (cauda equina in the lumbar region) and facilitate motion. Through its various ligament (and associated muscle) attachments, the posterior elements receive the different forces acting on the vertebra and channel them, via the pedicles, to the vertebral body.

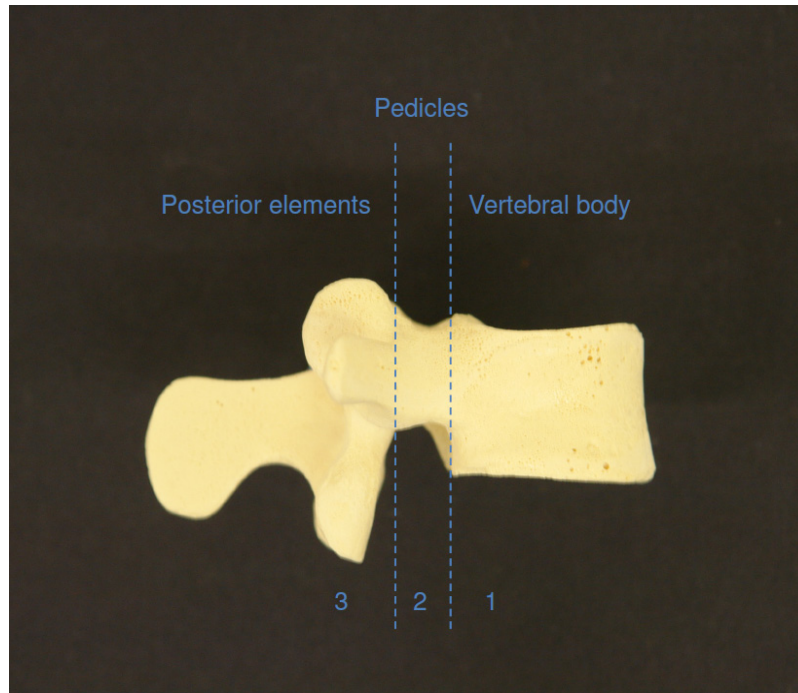


Figure 2.6 The division of a L3 vertebra into its three functional components.

2.4 Internal Fixation of the Spine

Bone screws placed in the pedicle are called pedicle screws (PSs). PSs are commonly used for fusions of the spine and to treat instability following tumours, trauma, scoliosis, spondylolisthesis (vertebra slippage) and various other spinal conditions (Crawford and Esses, 1994). These conditions often require hard stabilisation, or internal fixation, of the spine using various rods (Figure 2.7), plates, hooks and cages (Figure 2.8); bone screws are used to fix such hardware, or implants, to the spine (Vaccaro and Garfin, 1995). Medical grade titanium alloy is commonly used for the rods, plates and screws; titanium is a low density, hard metal with very good corrosion resistance (Hill, 1998). Furthermore, titanium and titanium alloys cause fewer artefacts in magnetic resonance imaging (MRI), commonly used

to monitor patients after spinal stabilisation, than other metals (particularly stainless steel) that could be used (Rudisch *et al.*, 1998). Poly-ether-ether-ketone (PEEK) is currently favoured for the interbody, or fusion, cages; PEEK is a high strength, radiolucent polymer that can be sterilised with gamma-rays (Hill, 1998). In spinal fusion, bone graft is placed within the fusion cage (Figure 2.8) to encourage bony ingrowth into the graft material to facilitate intervertebral fusion (Kurtz and Edidin, 2006).

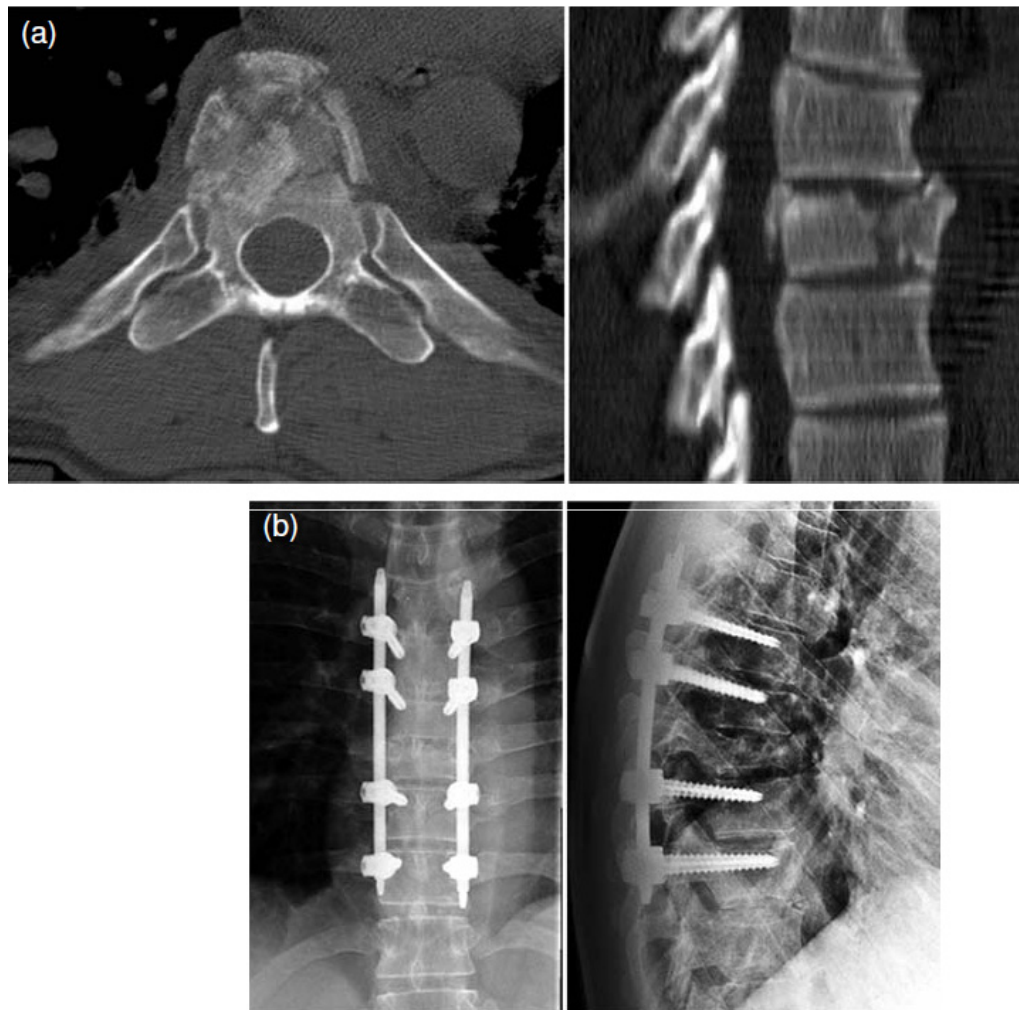


Figure 2.7 (a) Pre-operative computed tomography (CT) scan of a 32-year-old patient with a fractured T8 vertebral body, as a consequence of a car crash, (b) eight months after stabilisation using rods and screws (Palmisani *et al.*, 2009). *With kind permission from M. Palmisani and Springer Science + Business Media.*

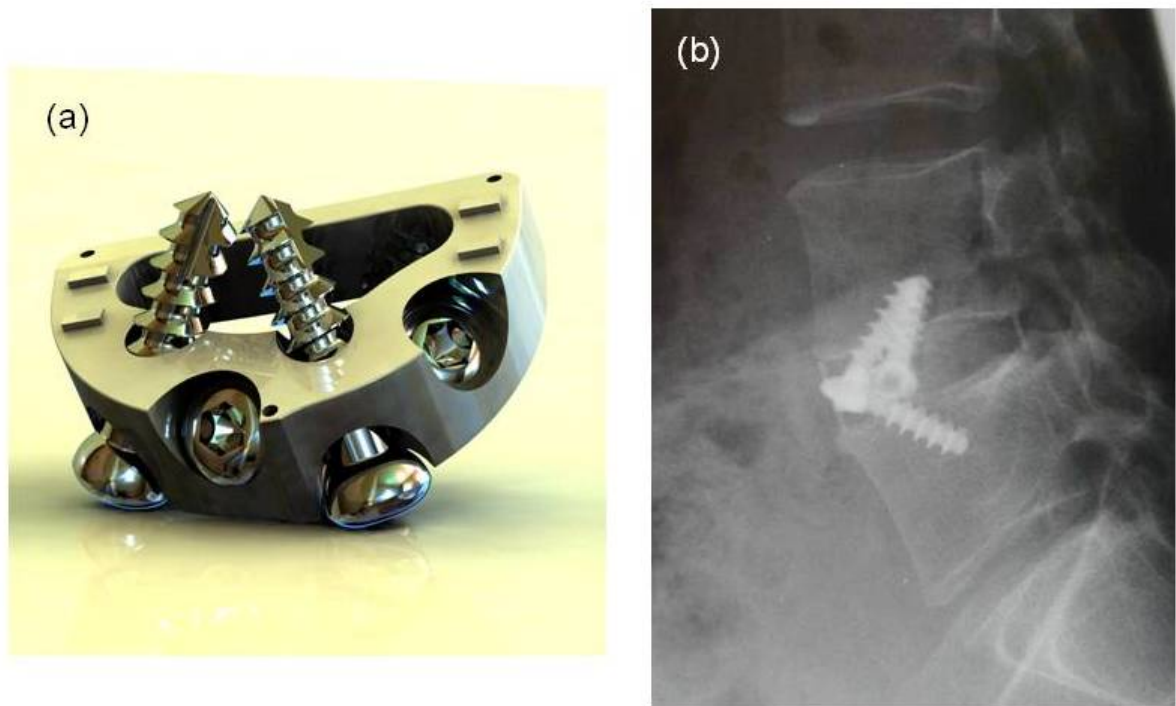


Figure 2.8 (a) A rendered image of a STALIF TT™ ‘stand alone’ anterior lumbar interbody fusion cage (made from PEEK) with titanium alloy screws, (b) X-ray of the radiolucent STALIF TT™ implanted *in-vivo*. Images kindly supplied by Surgicraft Ltd. (Redditch, UK).

To insert the spinal implants, the use of minimally invasive surgery (MIS) is increasingly favoured over traditional open surgery; by definition, MIS involves smaller incisions and less extensive surgical manipulation of the tissues surrounding the target structure (Guyer *et al.*, 2003). Considered as a recent development, the ultimate aim of MIS is to reduce the morbidity associated with traditional open surgery, but without hindering the surgeon’s ability to perform a successful operation (German and Foley, 2005). Therefore, it is important to note that MIS is an evolving discipline; long-term outcome studies are required to validate the new spinal techniques (German and Foley, 2005).

2.5 The OP Spine

2.5.1 Osteoporosis

Osteoporosis is a disease in which bone is weakened because resorption exceeds deposition (Silverthorn, 2001). Figure 2.9 illustrates the difference between normal and OP bone; a reduction in bone quantity and weak, thin trabeculae are found in OP bone. Both cortical and cancellous bone can be affected by osteoporosis, but it has a far greater effect on cancellous bone than cortical bone (Lauretani *et al.*, 2006; Santoni *et al.*, 2009). Whilst osteoporosis is not age- or gender-specific, it is more common in women and the elderly; in England and Wales, 50% of women and 20% of men will suffer an osteoporosis-related fracture after the age of 50 (Van Staa *et al.*, 2001). Factors that play a role in bone loss, and therefore increase the risk of osteoporosis, include: genetics, increasing age (natural bone loss), a low-calcium diet, lack of physical activity, low bone mineral density, smoking, alcohol abuse, hormonal imbalances, low vitamin D levels (vitamin D helps the body absorb calcium) and the intake of corticosteroid tablets (National Osteoporosis Society, 2006).

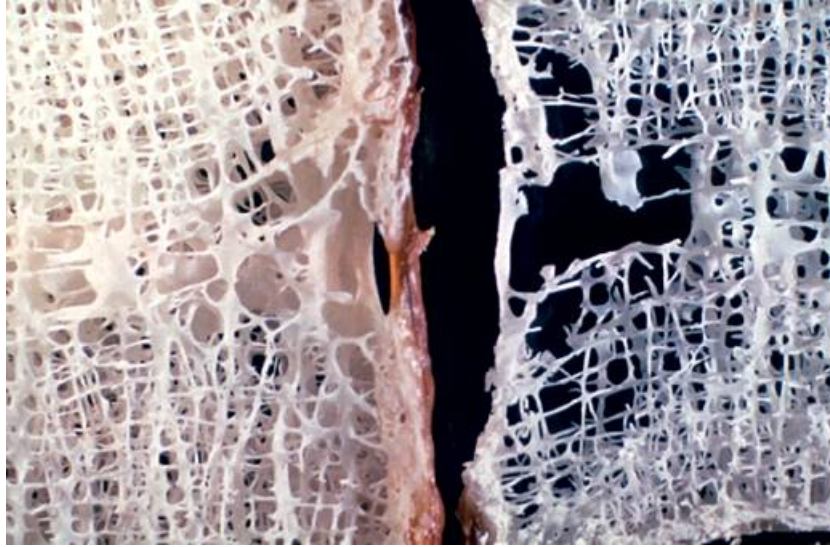


Figure 2.9 Comparison of a normal (*left*) and OP (*right*) lumbar vertebra. © DR. MICHAEL KLEIN / Still Pictures. Reproduced with kind permission.

2.5.2 Microstructure of Cancellous Bone

Bone contains organic components (mainly collagen), a mineral component (that resembles poorly crystalline hydroxyapatite) and water (Harries *et al.*, 1988; Lees *et al.*, 1983; Mkukuma *et al.*, 2004). As described in §2.3.3, bone can be divided into cortical and cancellous types. Cortical bone appears solid (approximately 5 – 30 % porosity); the only microscopic spaces present are resorption sites or canals containing capillaries and nerves. Cancellous bone, however, is a porous material (30 – 90 % porosity) and is composed of bony struts called trabeculae that join to form a network (Behiri and Vashishth, 2000). In between the trabeculae are interconnecting pores filled with marrow. This thesis is concerned with the fixation of screws into cancellous bone, such as that found in the centre of the vertebral body; therefore, this section considers the architecture and characterisation of cancellous bone.

The network of trabeculae within cancellous bone is such that the sizes of the pores vary considerably throughout the bone interior and thus present a structure of variable porosity. The arrangement of the trabeculae is functional; their orientation closely parallels the trajectories of maximum stress. In the vertebral body, three orientations of trabeculae exist; one vertical, one inferior oblique and one superior oblique system (McGill, 2000). Overall, the vertebral body is dominated by a system of columns of bone with much smaller transverse bony ties.

The microstructure of cancellous bone can be characterised by various morphological parameters, which include (Nazarian *et al.*, 2006; Stauber and Muller, 2006): bone volume fraction (bone volume/total volume, i.e. BV/TV), bone surface density (bone surface area/total volume, i.e. BS/TV), specific bone surface (bone surface area/bone volume, i.e. BS/BV), trabecular thickness (Tb.Th), trabecular spacing (Tb.Sp), trabecular number (Tb.N), connective density (Conn.D) and degree of anisotropy (DA). These parameters have been measured using stereological methods on two-dimensional (2D) images of bone biopsies (Parfitt *et al.*, 1983; Whitehouse, 1974), and now more recently using three-dimensional (3D) techniques involving micro-computed tomography (μ CT) (Chen *et al.*, 2008; Hildebrand *et al.*, 1999; Nazarian *et al.*, 2006; Stauber and Muller, 2006; Yeni *et al.*, 2009).

Clinically, osteoporosis is defined as loss of bone (osteopenia) to an extent sufficient to result in fracture with minimal trauma (Dequeker *et al.*, 1994). Osteoporosis is commonly diagnosed using dual-energy X-ray absorptiometry (DEXA) (Anon., 1992). DEXA facilitates the measurement of bone mass (bone mineral content, BMC) and areal bone mineral density

(BMD) (Beck, 2003). As well as reporting the measured density, DEXA results are often reported as a T-score; this is a comparison of a patient's BMD to that of a healthy thirty-year-old of the same sex and ethnicity (WHO Scientific Group, 2003). The criteria of the World Health Organisation (WHO) regarding T-scores are that: normal is a T-score of -1.0 or higher, osteopenia is defined as less than -1.0 and greater than -2.5, whilst osteoporosis is defined as -2.5 or lower (meaning a BMD that is 2.5 standard deviations below the mean of a thirty year old man/woman).

Age-related changes in the microstructure of vertebral cancellous bone have shown that Tb.Th and Tb.N is reduced; there are fewer trabeculae and the remaining trabeculae are both thinner and longer (Mosekilde, 1989; Snyder *et al.*, 1993) (Figure 2.9). Both of these changes in Tb.Th and Tb.N are strongly correlated with reductions in BV/TV (Bergot *et al.*, 1988; Snyder *et al.*, 1993); the range for BV/TV is considerably lower in OP patients than those observed in normal bone (Nazarian *et al.*, 2006). Another observed change in the microstructure of vertebral cancellous bone with aging is the decreased connectivity of trabeculae in both men and women (Chen *et al.*, 2008); this can be considered as secondary to reductions in the Tb.N (Goldstein *et al.*, 1993; Odgaard and Gundersen, 1993; Silva and Gibson, 1997). The non-uniform network of trabeculae in cancellous bone means that it exhibits a high degree of anisotropy (Hildebrand *et al.*, 1999); this is more apparent in OP bone, where the interaction between the bone microstructure and BV/TV will provide very site-specific properties (Nazarian *et al.*, 2006).

2.5.3 Internal Fixation of the OP Spine

In the OP spine, the resulting loss or weakening of bone often leads to fractures; 120,000 vertebral fractures are reported to occur each year in the UK (National Osteoporosis Society, 2006). This prevalence is expected to increase as the life expectancy in the UK continues to rise by 2 years in every decade (Gjonça *et al.*, 2005). Many vertebral fractures are caused by everyday activities such as bending or lifting light loads (Myers and Wilson, 1997). Fractures in the spine can cause progressive loss of height and abnormal spinal curvature, prompting a need for fixation of implants to aid repair. Screw fixation can be extremely difficult in OP bone because of its reduced strength (Halvorson *et al.*, 1994; Wittenberg *et al.*, 1991). Internal constructs in the OP spine have been reported to fail due to screw loosening and loss of fixation at the screw-bone interface (Halvorson *et al.*, 1994; Okuyama *et al.*, 1993; Soshi *et al.*, 1991; Wittenberg *et al.*, 1991; Zindrick *et al.*, 1986). The work in this thesis attempts to address this problem.

Other surgical interventions in the OP spine include two treatment options for vertebral compression fractures: vertebroplasty and kyphoplasty. Vertebroplasty involves the percutaneous injection of bone cement into a fractured vertebral body; a reduction in fracture pain has been reported (Barr *et al.*, 2000). In kyphoplasty, an inflatable bone tamp/balloon is inserted into the vertebral body to elevate the collapsed end plates to their original height; the resulting cavity is then filled with bone cement under low pressure (Garfin *et al.*, 2001). Unlike vertebroplasty, kyphoplasty has the additional benefit of spinal deformity correction; reports of bone cement leakage into the spinal canal are also rare with kyphoplasty (Garfin *et*

al., 2001; Ledlie and Renfro, 2003). These procedures will not be discussed further as they are beyond the scope of this thesis, which is focused on screw fixation in the OP spine.

2.6 Screw Pullout Strength

Pullout force can be used to measure screw fixation strength (Thompson *et al.*, 1997). A wealth of studies in the literature report screw pullout strength from various test materials (Becker *et al.*, 2008; Cook *et al.*, 2004; Cordista *et al.*, 2006; Gausepohl *et al.*, 2001; Hashemi *et al.*, 2009; Inceoglu *et al.*, 2006). Direct screw pullout acts as a “worst case” scenario for the loss of implant fixation; screw pullout is a simple test that enables results from different researchers to be compared. Part of the work in this thesis will concentrate on screw pullout testing and failure within a material intended to model the properties of bone.

2.7 The Use of Bone Models in Biomechanical Tests

There are several difficulties in using human tissue for biomechanical tests. Firstly, human tissue is not readily obtainable; use of it requires ethical approval and lengthy, bureaucratic procedures usually need to be followed. Secondly, considerable biological variability exists among cadaveric specimens, which limits their reproducibility. Variations in the specimen age, sex, sample location, the degree of osteoporosis and other pre-existing metabolic conditions account for some of the differences in mechanical properties found across cadaveric specimens (Sommers *et al.*, 2007; Szivek *et al.*, 1993). In a given sample, any

small differences can be difficult to characterise because of the inherent variance; a very large bone sample size is required for that sample to be a useful representation of the desired population (in terms of significant statistical comparisons), which further amplifies the availability issues with bone. Thirdly, human tissue degrades over time (Cristofolini *et al.*, 1996), making it difficult to preserve in test conditions and, fourthly, natural bone is generally expensive to purchase (Johnson and Keller, 2008).

Synthetic bone test specimens are often used in favour of cadaveric specimens, because of their low variance in material properties, availability (when compared to cadaveric specimens), shortened test times, and for the uncontaminated and clean test environment that they provide. Rigid, closed cell polyurethane (PU) foams, with densities typically ranging from 0.16-0.64 g.cm⁻³, are widely used as standard test materials for mimicking human cancellous bone (ASTM F1839-08, 2008). The PU foam is available in blocks, which have been used to investigate fixation of bone screws (Battula *et al.*, 2006; Chapman *et al.*, 1996), and will be used in this form for the work in this thesis. PU foam is also used as a cancellous core material in whole bone models, with an outer coating to feature cortical bone; these models have been used to investigate devices such as intramedullary nails (Iesaka *et al.*, 2005). The mechanical properties of the whole bone models have been compared with those of natural bone and were found to be similar (Heiner and Brown, 2001). Chapter 4 describes a study on the strength and stiffness of commercially available PU foams as mechanical models for OP human cancellous bone.

It is important to note the differences in microstructure between PU foam and cancellous bone. PU foam is available in an open-cell or closed-cell structure. Open-cell PU foam is a better approximation of the cancellous bone microstructure; it has a 95% open-cell structure with cell sizes ranging from 1.5 - 2.5 mm (Sawbones® Europe AB, Malmö, Sweden) and wall thicknesses in the range of 0.2 – 0.3 mm (Johnson and Keller, 2008). If these values are compared with human cancellous bone, which has a Tb.Sp range of 0.4 – 1.4 mm (Chen *et al.*, 2008; Hildebrand *et al.*, 1999; Stauber and Muller, 2006) and a Tb.Th range of 0.1 – 0.2 mm (Chen *et al.*, 2008; Fyhrie and Schaffler, 1994; Nazarian *et al.*, 2006), then it is apparent that the pore sizes are smaller in cancellous bone than open-cell PU foam (Johnson and Keller, 2008). However, open-cell PU foam provides a useful continuum of pores within which to study screw fixation; the assumption of pore continuum has also been used in finite element analysis of cancellous bone (Hosokawa, 2008). Closed-cell PU foam has a 95 - 99.9 % closed-cell structure (Sawbones® Europe AB, Malmö, Sweden); this provides a uniform and consistent test bed that is suitable for comparative testing of bone screws and other medical devices.

2.8 Key Points

- Bone screws, including PSs, are used to fix various rods, plates and cages to the spine, following deformity and/or disease.
- Osteoporosis is an increasingly prevalent disease that reduces bone strength.
- Screw fixation in OP bone is a problem; the bone strength is reduced, which can result in the loosening of spinal implants and subsequent failure.
- Screw pullout tests, coupled with the use of synthetic bone models such as PU foam, can be used to study screw fixation in OP bone; this is the basis for the work in this thesis.

3. CURRENT PRACTICE OF PEDICLE SCREW SURGERY IN THE UK AND IRELAND: A QUESTIONNAIRE STUDY

3.1 Chapter Overview

This chapter presents work conducted in the form of a questionnaire study. The study investigates pedicle screw (PS) surgery, and the use of associated instrumentation, throughout the UK and Ireland. Section 3.2 provides some background information explaining why the study was undertaken. Section 3.3 describes a preliminary survey study, which led to the main investigation outlined in §3.4. Section 3.5 explains how the main questionnaire study was conducted. Section 3.6 presents the results, which are discussed in §3.7. The core findings from the questionnaire are summarised in §3.8.

3.2 Introduction

The literature reports several complications associated with PS surgery; these can be divided into screw-related and surgical complications (Boos and Webb, 1997). Screw-related complications include screw breakage, screw loosening, screw cut out and screw pullout (Esses *et al.*, 1993). Surgical complications include unrecognised screw malpositioning, pedicle fracture, cerebral spinal fluid (CSF) leak, vessel injury, deep infection and permanent nerve root injury (Esses *et al.*, 1993).

Of all these complications, screw malpositioning remains a problem, with Schulze *et al.* (1998) reporting that approximately 20% of PSs are implanted inaccurately by experienced surgeons. In treating the difficult condition of neuromuscular scoliosis, Modi *et al.* (2008) reported that 27% of PSs (273 out of 1,009 screws) were inaccurately placed outside the pedicle. Such high rates of screw malpositioning have led a trend towards the use of navigational aids in PS surgery. In recent years, pedicle probes, three-dimensional (3D) image intensifiers, intra-operative computed tomography (CT) and computer-assisted image-guided navigation systems have reportedly reduced the rate of malpositioned PSs in patients (Kosmopoulos and Schizas, 2007). However, these navigational aids are often expensive and limited in availability; not all hospitals undertaking PS surgery have access to this technology. Other limitations of navigational aids include radiation exposure for the surgical team, increased surgery time and corresponding higher infection rates (Holly, 2006; Holly and Foley, 2003). Furthermore, the physical limitations of navigational systems are notable in cases where the imaging of very obese patients or the upper thoracic spine has been difficult (Nowitzke *et al.*, 2008). Thus, consideration should be given to the idea of a simple mechanical device to aid PS insertion, which would not involve the disadvantages mentioned previously.

3.3 Preliminary Market Survey at BritSpine 2006 Conference

3.3.1 Introduction

As an initial step in gauging response to the idea of a simple mechanical device to aid PS insertion, a preliminary market survey was performed at the BritSpine 2006 conference, held on 26 to 28 April 2006 at the Cardiff International Arena (Cardiff, UK). The BritSpine conferences occur every two years and are well attended by the majority of spine surgeons in the UK; BritSpine is a combined meeting of the British Scoliosis Society, British Cervical Spine Society, British Association of Spinal Surgeons and the Society for Back Pain Research. The 2006 conference attracted approximately 300 delegates and provided a good opportunity to discuss the research ideas in this thesis.

3.3.2 Method

The aim was to target surgeons, during break sessions, who were either experienced consultants or specialist registrars. Each surgeon was asked whether they had worked with PSs and whether they would mind discussing a mechanical pedicle aiming device (sometimes referred to as a jig). In each case, it was stated that any device design would be based upon a general consensus and that the author was simply asking for each surgeon's opinion on an idea that was already in place. The style of interview was unstructured and was developed as

a conversation. In general, more than one surgeon was approached at a time and discussion was usually initiated between a pair of surgeons and the author. The core questions asked to the surgeons were as follows:

- What is your opinion on a simple mechanical device to aid PS insertion?
- Have you used a computed navigation system to insert PSs? If so, did you find the system useful?
- Have you had problems with PS placement in patients?
- Have you experienced problems in treating patients with an osteoporotic (OP) spine?

These questions were helpful in determining the main questions to be addressed in the subsequent questionnaire study (§3.4 to §3.8).

3.3.3 Results

The preliminary survey provided the opinions of 19 medical professionals with the following breakdown:

- 14 consultant neurosurgeons/orthopaedic surgeons.
- 4 specialist registrars.
- 1 senior house officer.

Notable results from the preliminary survey were that 68% of participant surgeons expressed a need for a simple mechanical device to aid PS insertion, and that 74% of participant surgeons would not use a computed navigation system during surgery.

The qualitative results from the preliminary survey can be summarised by the main questionnaire findings; in the interest of focus, the results from the preliminary survey are provided in Appendix A.

3.3.4 Limitations of the Preliminary Survey (Points Noted for the Main Survey)

The quality of the preliminary survey raised issues regarding survey reliability. As a consequence of the conversational method used, not all areas may have been addressed to each and every surgeon (e.g. whether a jig will add extra time to surgery – this was not asked to everyone). No standard set of questions was asked to every surgeon; a discussion was initiated by asking a starter question as to whether there was a need for a jig to aid PS placement. The influence of one surgeon's opinions on the other surgeon during the conversations may have led to bias. Thus, the preliminary survey findings cannot guarantee a true reflection of the individual surgeon's opinion.

In hindsight, the distinction between those survey contributors that were neurosurgeons and those that were orthopaedic surgeons would have been useful. Unfortunately this separation was not made at the time of the survey. Such a division may have provided a difference in thinking between the two sub-set groups of surgeons. Perhaps the neurosurgeons, who are sometimes perceived as being more meticulous, may have been more favourable to the idea of a pedicle jig.

3.3.5 Conclusions

The BritSpine 2006 preliminary market survey highlighted an interest amongst surgeons in the idea of a PS aiming jig. Comments were generated not only on the pedicle jig, but also on the issue of screw fixation in the OP spine. The survey results were found to be more qualitative than quantitative, with most of the information proving useful in the development of a more comprehensive questionnaire aimed at a larger group of spine surgeons.

3.4 Purpose of the Main Investigation

The purpose of the main investigation was to determine the relevance and importance of a simple device to aid PS placement, to collect opinions and experiences on PS surgery in the UK and Ireland and to determine the design criteria for a simple device to aid PS placement. No previous study has examined the current practice of PS surgery in the UK and Ireland. To the author's knowledge, no similar studies have been conducted in other countries; although several reports on patient-orientated questionnaires do exist, which mainly concern the outcome and/or long-term (several years) follow-up of various PS operations (Booth *et al.*, 1999; Christensen *et al.*, 2002; Freeman *et al.*, 2000; Gehrchen *et al.*, 2002; Grob *et al.*, 2005; Remes *et al.*, 2004; Rivet *et al.*, 2004). The present study may aid in determining whether there is a need to standardise the assessment method for PS placement in patients.

3.5 Method

3.5.1 Questionnaire Development and Administration

A questionnaire (see Appendix B) was designed in consultation with a statistician who has experience in questionnaire design (Mrs E. Aspinwall, School of Mechanical Engineering, University of Birmingham, UK) and industrial partners (Mr A. Fennell and Mr S. Trotman, Surgicraft Ltd., Redditch, UK); the process that was undertaken to determine the questionnaire questions involved drafting several versions of the questionnaire until there was mutual agreement on the final version. In March 2007, the postal questionnaire was sent to 422 surgeons on a list provided by Surgicraft Ltd. (Redditch, UK). The list accounted for the majority of surgeons known to perform spinal surgery in the UK and Ireland. No other criteria were applied to the selection of surgeons to which the questionnaires were sent to. A business-reply service allowed surgeons to send their responses via postal mail.

The questionnaire title page acted as a covering letter, describing the purpose of the study and providing a date by which the completed questionnaire should be returned. The respondents were given 3 weeks to reply. A sheet to record the surgeon's speciality and current position followed the title page; no personal details were requested and it was stated that all responses will be treated with the utmost confidence, and that the questionnaire results will only be presented in aggregated format. This sheet also included brief instructions on completing the questionnaire and stated that respondents were encouraged to discuss their responses with

colleagues, such that their responses do not have to be based on their specific surgical experience. The questionnaire consisted of 11 questions:

- 1) Do you think there is a need for a simple device to aid PS placement? Please give reasons for your answer.
- 2) What spinal systems do you currently use to aid PS placement?
- 3) What are the good features and limitations/shortfalls of these particular spinal systems that you use?
- 4) What is your idea of the 'perfect' PS path/entry point/trajectory for the positioning of a PS?
- 5) In which regions of the human spine have you inserted PSs?
- 6) Have you experienced any problems with PS placement in patients? If yes, please specify the problems.
- 7) **(a)** In your opinion, which regions of the human spine would benefit from a simple device to aid PS placement?
- 7) **(b)** Why do you think this?
- 8) Preferences for a simple device for PS placement.
- 9) What problems, if any, have you experienced with PSs in treating patients with an OP spine?
- 10) Historically, do you know of any screws that have been designed for OP bone? If yes, were these screws successful or unsuccessful in OP bone?

- 11)** Do you have any other suggestions or opinions about PSs, systems to assist spinal surgery, the design of a PS placement device or osteoporosis in the spine?

Some of these questions were designed to generate a single answer only, whilst some were designed to encourage an open answer, and the other questions were designed to produce multiple answers (where applicable). Following receipt of the completed questionnaires, any similar statements provided by the surgeons were grouped to form common headings.

3.5.2 Statistical Analysis

The study sample was described by calculating the frequencies and percentages for categorical variables. For Question 1 and Question 6, Chi-squared testing (Bland, 2000) was used to test for any association between surgeon speciality (i.e. orthopaedic surgeon or neurosurgeon) and question response (i.e. yes or no); statistical comparisons were made using MINITAB® Release 15 Statistical Software (Minitab Inc., Pennsylvania, USA). The significance level was set at 0.05 for all tests.

3.6 Results

3.6.1 Response Rate

101 questionnaires (24%) were returned; 67 of these (16% of total sent out) were useful (i.e. completed questionnaires) whilst the remainder had been returned as blank questionnaires. 66 out of 67 respondents were consultant surgeons; the remaining respondent did not specify their current position at the time the questionnaire was sent out. Table 3.1 summarises the specialities of the 67 surgeons that completed the questionnaire. The majority of respondents (75%) were orthopaedic surgeons.

Table 3.1 Breakdown of surgical speciality for the 67 questionnaire respondents.

Surgeon's speciality	Total number
Neurosurgeon	14
Orthopaedic surgeon	50
Spinal surgeon	1
Unanswered/Are not any of the above	2

3.6.2 Q1. Do you think there is a need for a simple device to aid PS placement? Please give reasons for your answer.

Over half of the respondents answered “yes” to Question 1 (Figure 3.1). Respondents in favour of a simple device to aid PS placement admitted to a relatively high percentage of PSs placed unintentionally outside the pedicle (e.g. one surgeon placed 23% of screws outside the pedicle in the lumbar spine). The reduced risk of neurological/vascular complications, reduced incidence of pedicle breach, reduced X-ray exposure, increased confidence, increased accuracy, use as a training tool for inexperienced surgeons, use as a supplement aid and an increased rate of correct screw placement were highlighted as potential benefits of using a simple device. Emphasis was placed on using a simple device to correctly position screws in considerably deformed/degenerated spines. The device was also favoured for use in revision cases and for use in the thoracic spine and the cervical spine (if a surgeon chooses to perform pedicle fixation in this region), which were considered non-standard situations that are not conducted as often as lumbar and sacral pedicle fixation.

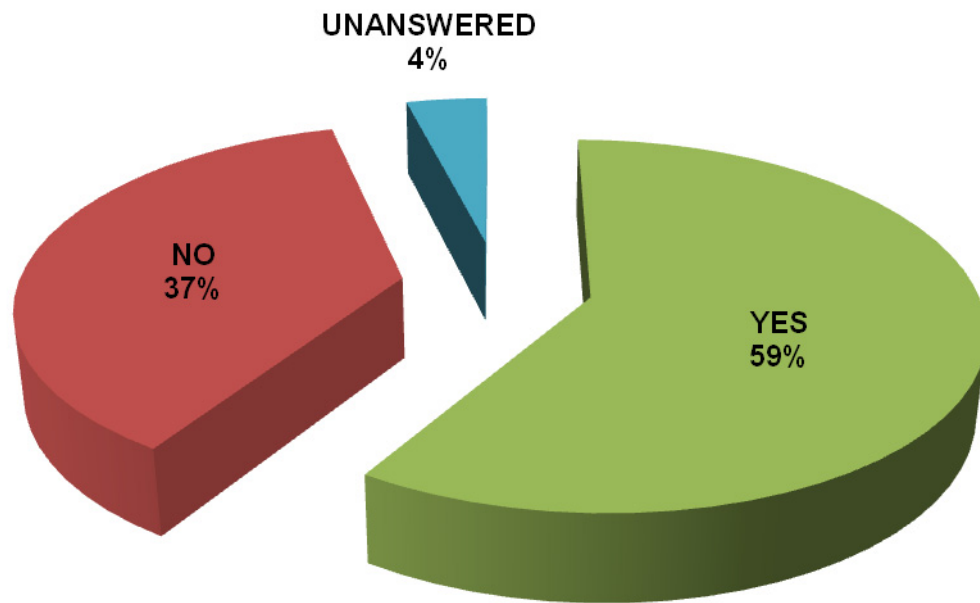


Figure 3.1 Response to Question 1: Do you think there is a need for a simple device to aid PS placement?

Respondents not in favour of a simple device to aid PS placement noted that high resolution X-ray image intensifiers, CT, magnetic resonance imaging (MRI) and anatomical knowledge are enough to assist in PS surgery. Experienced surgeons that regularly carry out PS surgery (one surgeon places 50-60 PSs at multiple levels every week) stated they would not require an additional device. Other comments included: the devices not having proper track records; the belief that they already exist (but offer no advantage); the belief that navigation systems are cumbersome and expensive. It was also noted that, in many cases, the pedicle is breached deliberately and necessarily. Furthermore, respondents explained that blind placement with the aid of a device would lead to the use of PSs by surgeons unfamiliar with the anatomy, and therefore unfamiliar with the clinical indications.

A Chi-squared test (Bland, 2000) with a null hypothesis of no association between surgeon speciality (i.e. orthopaedic surgeon or neurosurgeon) and question response (i.e. yes or no) was performed using a 0.05 significance level; no significant difference ($p = 0.984$) was found between the neurosurgeons and orthopaedic surgeons in their response to Question 1 because $p > 0.05$.

3.6.3 Q2. What spinal systems do you currently use to aid PS placement?

The majority of respondents (55%) did not use any systems to aid PS placement; 2% used the systems specified in the question (Table 3.2); 43% used other systems (Table 3.3). The majority using “other” systems (52%) used C-Arm X-ray image intensifiers.

Table 3.2 Spinal systems used by the respondents to aid PS placement (as specified in Question 2).

System	Respondents that use the system (%)
PediGuard® (SpineGuard S.A., St Mandé, France)	2
SpineAssist® (MAZOR Surgical Technologies Ltd., Caesarea, Israel)	0
CD HORIZON® SPIRE™ Spinal System (Medtronic Sofamor Danek, Memphis, Tennessee, USA)	0
None	55
Other(s)	43

Table 3.3 Breakdown of “Other(s)” spinal systems used by the respondents to aid PS placement (follow-on from Question 2).

Other spinal systems used	Respondents that use the system (%)
C-Arm X-ray image intensifier	52
Touch/feel	11
Special probe designed by a surgeon 20 years ago	3
Anatomy/landmarks/hand-eye	8
Mehdian™ pedicle screw system (Corin Group PLC, Cirencester, UK)	3
The StealthStation® iNAV™ (Medtronic Navigation, Louisville, Colorado, USA)	8
PRAXIM Medivision navigation system (PRAXIM Medivision SA, Grenoble, France)	3
BrainLAB VectorVision® Spine (BrainLAB AG, Feldkirchen, Germany)	3
Cannulated screws (Ulrich GmbH & Co.KG, Ulm, Germany)	3
Unanswered question	3
Unclear answer	3

3.6.4 Q3. What are the good features and limitations/shortfalls of these particular spinal systems that you use?

Most respondents found the specified systems (Table 3.2 and Table 3.3) easy to use, safe and accurate (Table 3.4). The 3D images provided by some systems, e.g. PRAXIM Medivision navigation system (PRAXIM Medivision SA, Grenoble, France), were considered a major asset. Common limitations were the associated learning time and increased surgery time, as well as high cost and the inability to deal with all spinal conditions.

Table 3.4 Good features and limitations/shortfalls of the spinal systems used by the respondents (Question 3).

Spinal system used	Good features	Limitations & shortfalls
PediGuard® (SpineGuard S.A., St Mandé, France)	Likened as a PS "parktronic" system.	Noisy.
	Easy to use.	Different feel to normal pedicle finder.
		Sensitivity problems.
		Expensive.
		Delicate.
		Slightly short probe.
C-Arm X-ray Image Intensifier	Quick.	X-ray dose to patient and surgical team.
	Available at all hospitals.	Difficult with scoliosis.
	Good visualisation.	Need to move image intensifier.
	Helps with ideal placement & most appropriate angles in the lumbar/thoracic spine.	Does not provide a 3D image; risk of encroaching on the spinal canal.
	Easily adjustable.	Difficult with small pedicles.
	Portable.	Occasional image quality problems.
		Inexperienced staff.
		Learning curve for junior staff.
Touch/feel	Increased certainty of placement.	Does not provide 100% certainty.

Special probe designed by a surgeon 20 years ago	Safe method. Inexpensive.	Not good for porotic bone.
Mehdian™ pedicle screw system (Corin Group PLC, Cirencester, UK)	Simple. Easy to use.	
The StealthStation® iNAV™ (Medtronic Navigation, Louisville, Colorado, USA)	Accurate.	Increased surgery time.
	Provides security.	Heavy reliance on imaging.
PRAXIM Medivision navigation system (PRAXIM Medivision SA, Grenoble, France)	Provides 3D images.	Long set-up and training time.
	Accurate.	Bulky.
		Complex equipment; prone to breaking down.
BrainLAB VectorVision® Spine (BrainLAB AG, Feldkirchen, Germany)	Easy to use.	No real-time pictures.
Cannulated screws (Ulrich GmbH & Co.KG, Ulm, Germany)	Easy to insert using a guide wire.	

3.6.5 Q4. What is your idea of the ‘perfect’ PS path/entry point/trajectory for the positioning of a PS?

3.6.5.1 General Comments

Respondents either provided general (this section) or region-based descriptions/sketches (§3.6.5.2 to §3.6.5.5) for PS placement. Vague descriptions/sketches were discarded for Question 4. The ideal positioning technique would have the following characteristics:

- using the facet joint bone as a landmark to expose the pedicle;
- using lateral plane and anterior-posterior plane X-ray films (when 2 screws are inserted at the same level), to direct the screw medially to the “projected” point of intersection with the opposite side, in the anterior third of the vertebral body;
- tailoring each screw trajectory to the anatomy of the spinal element(s) captured by the screw;
- choosing a screw path that does not involve any secondary soft tissues;
- placing the screw within the cortical margins of the pedicle, without breaching the bone (less important in cases such as extradural tumours);
- placing the screw parallel to the superior end-plate, such that the screw reaches just short of the anterior vertebral body.

The following characteristics summarise what should be *avoided* during ideal PS positioning:

- using a lateral approach through the lateral pedicle wall;

- allowing screw penetration through the anterior cortex (except in exceptional circumstances e.g. gross osteoporosis);
- allowing full triangulation of two PSs inserted at the same level, especially in kyphosis (abnormal outward curvature of the upper spine).

3.6.5.2 Cervical Spine

Respondents noted that the entry points for PSs in the cervical spine are as for lateral mass screws (these are placed in the lateral mass of the C1 vertebra, or atlas, where the bone is most bulky and solid) but directed medially. For C2, the mid-cervical region and C6/C7, a respective 25°-30°, 10°-15° and 0° lateral-medial screw angulation was recommended.

3.6.5.3 Thoracic Spine

Extra-pedicle to intra-pedicle approaches were not recommended for screw placement in the thoracic spine. Respondents advised that screws should be placed starting from a medial position, aiming straight down the pedicle axis. A common entry point was identified; between the base of the transverse process and laminar groove to the upper border of the transverse process, but the screw angle can be variable. For T1-T4, T5-T10 and T11/T12, a respective 10°-20°, 10° and 0°-10° lateral-medial angulation was recommended. For T11/T12, respondents also advised that the mammillary process should be amputated and that the screw should be directed anteriorly.

3.6.5.4 Lumbar Spine

As a screw insertion point, respondents advised using the mid-point of the mammillary process, on the transverse process, to the facet of the lumbar vertebra. They also recommended screw placement down the centre of the pedicle and just beyond halfway through the vertebral body, as seen on a lateral plane X-ray. For non-fusions of the lumbar spine, the Wiltse minimally invasive approach (Wiltse and Spencer, 1988) was recommended; this involves approaching the pedicle at the mid-point of the transverse process and laterally from the base of the superior articular process near the mammillary body (thus avoiding the facets). For fusions of the lumbar spine, the standard mid-line approach (Moshirfar *et al.*, 2006) was recommended; this involves placing the screw more medially to limit soft tissue retraction.

Respondents suggested the following screw trajectories for the ideal screw placement at different levels of the lumbar spine: for L2/L3 – slightly cephalad, for L4 – horizontal, for L5 – slightly caudal, plus a 15° lateral-medial screw angulation (to give an oblique path across the vertebral body). They noted that the postero-lateral approach to PS insertion increases screw pullout strength, and that 80% screw penetration is ideal for the lumbar spine.

3.6.5.5 The Sacrum

At the S1 level, respondents advised that the PS should ideally project in an antero-medial direction. To achieve good purchase, it was advised that the screw should engage with the anterior cortex of the sacral vertebra. A 25°-35° lateral-medial screw angulation at L5/S1 was also recommended.

3.6.6 Q5. In which regions of the human spine have you inserted PSs?

The number of respondents that have inserted PSs into the cervical spine is about half the number for the other regions (Figure 3.2).

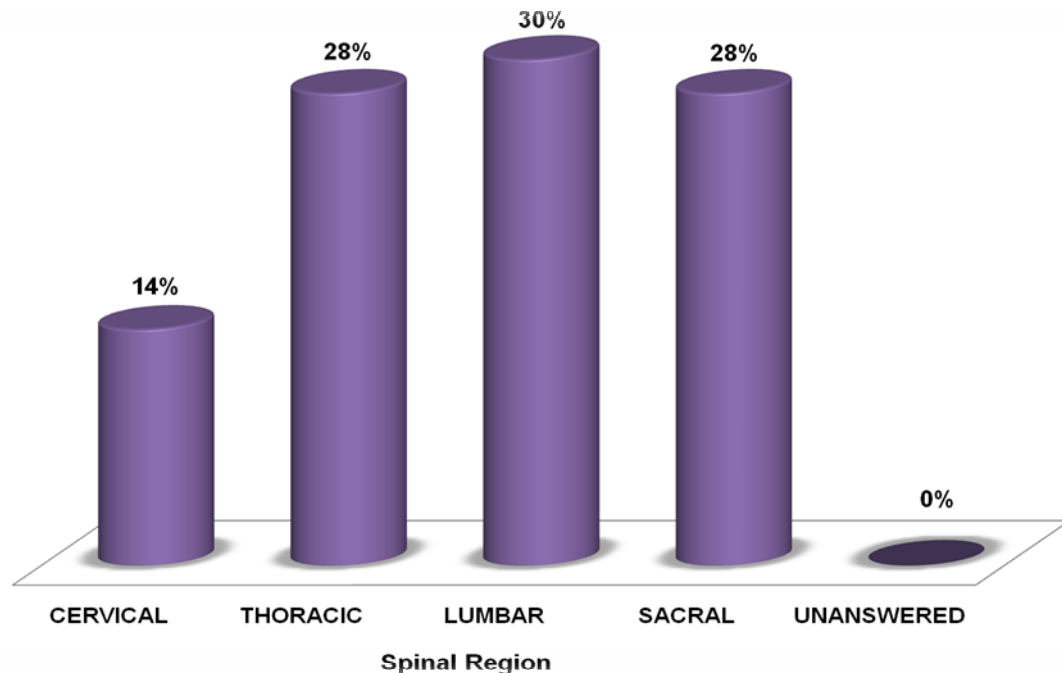


Figure 3.2 Regions of the human spine, shown as relative percentages, in which respondents have inserted PSs (Question 5).

**3.6.7 Q6. Have you experienced any problems with PS placement in patients?
If yes, please specify the problems.**

Seventy eight percent of respondents admitted to having experienced problems with PS placement in their patients (Figure 3.3); the specified problems were grouped into categories (Table 3.5). Table 3.5 also provides examples of some responses to Question 6.

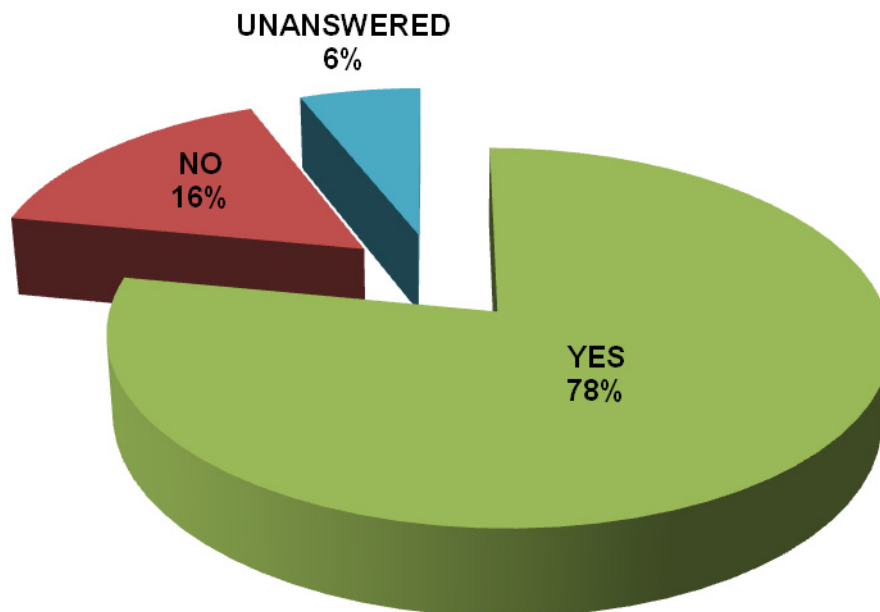


Figure 3.3 Response to Question 6: Have you experienced any problems with PS placement in patients?

Table 3.5 Problems encountered by the questionnaire respondents whilst undertaking PS surgery (Question 6).

Problem with PS surgery	Examples of surgeons' remarks
Treating scoliosis	Beware the degenerative scoliosis! Either too medial or too lateral. Dependent on vertebral rotation.
	Adult scoliosis.
Locating the pedicle	Defining the pedicle using an image intensifier can be very difficult.
	Missing pedicle numbers.
Breaching of the pedicle walls	Pedicle cortex breach.
	Medial (occasionally), inferior (rare) and lateral (infrequent) breach. Nerve root tension is relieved by removal and re-directing of screw.
Perforating the vertebral body wall	Commonest error encountered is when surgeons have gone too directly anterior in L5 or S1, perforating the lateral vertebral body wall and hitting the descending nerve root.
Screw malposition	Missing the pedicle.
	5% missed pedicle or not "ideal". No neurological or vascular injury as a consequence. 1% re-operation to shorten/change trajectory.
Hard bone	Very hard bone.
Screw loosening	Loosening.
	Poor hold - break out laterally.
Spinal cord & root irritation/damage	Nerve root irritation, i.e. screws too long. Catch exciting roots. Very rarely canal encroached - no cord damage.
	Spinal cord & root damage.
Anatomy	There will always be difficult screws due to variations in anatomy.
	Awkward anatomy.

Spinal deformity	Congenital abnormality with hard bone and need to drill out pedicle.
	Of course - especially in deformity work.
Revision surgery	Only in un-navigated patients, especially during revision surgery where landmarks have been destroyed.
	2 screws revised.
Spondylolisthesis (vertebra slippage)	Spondylolisthesis, especially grades II and III.
Pain	Radicular pain (pain that 'radiates' along nerves connected to the spine).
CSF leak	Dural leak on two occasions, but no neurological deficit.
Infection	Infection.
Small thoracic pedicles	Can be difficult in the thoracic spine due to the size of the pedicle.
	Incorrect thoracic placement.
Sacral region	Sacral "pedicles" can be difficult to locate.
	Sacral screws can be a problem with iliac crest (bone) overhang.
Pedicle fracture	Fracture of pedicle on occasion.
	Pedicle fracturing the bone.
Bleeding	Bleeding.
OP bone	1 loss of fixation in OP spine.
Stenotic (narrowed) pedicles	Stenotic pedicles.
Human error	This is relatively minor, with no sequela, generally due to human error.
Cancer	Cancer.
	Neurofibromatosis (tumours that cause soft bone and large foramina).

A Chi-squared test (Bland, 2000) with a null hypothesis of no association between surgeon speciality (i.e. orthopaedic surgeon or neurosurgeon) and question response (i.e. yes or no) was performed using a 0.05 significance level; the test found no significant difference ($p = 0.150$) between the neurosurgeons and orthopaedic surgeons and so their response to Question 6 was considered not to be significantly different because $p > 0.05$. However, the Chi-squared test, on which this statistical finding is based, was not strictly valid; see Appendix C for a further analysis.

3.6.8 Q7. (a) In your opinion, which regions of the human spine would benefit from a simple device to aid PS placement?

The results are listed in Table 3.6 and suggest that surgeons are less comfortable when performing PS surgery in the cervical and thoracic spine, compared to the lumbar and sacral regions.

Table 3.6 Regions of the human spine, shown as relative percentages, that respondents felt would benefit from a simple device to aid PS placement (Question 7a).

Spinal region	Respondents in favour of a simple device to aid PS placement in this region (%)
Cervical	24
Thoracic	29
Lumbar	20
Sacral	16
Not really necessary	3
Don't know	1
Unanswered/Have no view	7

3.6.9 Q7. (b) Why do you think this?

3.6.9.1 Cervical Region

Respondents found that the cervical spine has small pedicles, making it difficult to use PS fixation. Surgeons have encountered difficulty in defining the anatomy and judging the surface landmarks of this region. The wrong trajectory of PS placement can easily lead to spinal cord/vascular injury, which is why lateral mass plates are often preferred to stabilise the cervical spine, especially in the lower region. Thus, the idea of a PS aid for the upper cervical spine was accepted with caution by the respondents. The benefits of a successful pedicle aid included achieving a better hold in this region and that it could encourage surgeons to use PSs in the cervical spine.

3.6.9.2 Thoracic Region

Respondents highlighted the thoracic spine as the most difficult region for PS surgery. They felt there was more need for a pedicle aid in the mid to upper thoracic spine, because of the higher risk to neurological structures. One respondent commented that the T4-T8 region may have very small pedicles and the “numerous tissue planes and density differences make realisation with image intensification very difficult.” Respondents noted that the risk of spinal cord injury is increased further in the case of scoliosis, where determination of the screw trajectory can be difficult. Another respondent, in favour of an aid, noted that surgeons

often prefer to be safe and place screws “too laterally” in the thoracic spine, increasing the risk of screw pullout. Respondents felt that a successful pedicle aid should be less cumbersome than an image intensifier; a device that thoracic PS surgery is currently dependent on. As with the cervical spine, a pedicle aid may encourage some surgeons to use PSs in the thoracic spine.

3.6.9.3 Lumbar Region

Respondents found the lumbar spine favourable for PS surgery. They noted that screw malpositioning carries less risk of neurovascular injury in the lumbar spine; because the pedicles are larger and vary less. A pedicle aid was not seen as necessary, but may be useful in cases involving scoliosis, narrow pedicles, revision surgery and for “finding the pedicle when landmarks are lost/distorted.”

3.6.9.4 Sacral Region

Respondents noted the need for a good foundation to lumbar/sacral fusion using long PSs; however, accurate screw placement was not seen as critical because of the large target area. An aid was favoured in this region for revision cases, tumours, “when landmarks are lost/distorted” and for “overweight patients, where the sacral region can be a difficult area to image.”

3.6.10 Q8. Preferences for a simple device for PS placement.

This question consisted of 8 sub-questions; the answers are shown in Figure 3.4. There was no clear consensus in the answers given; however, if the majority opinion is taken for each of the design factors in Question 8, then the overall preference was for a device that is multiple use, one-piece, hand-held, radiolucent (transparent to X-rays), unilateral (fits on to a single pedicle) and uses the line of sight principle in traditional open surgery, with no preference as to whether the PS should be loaded into the device before or after entering the body.

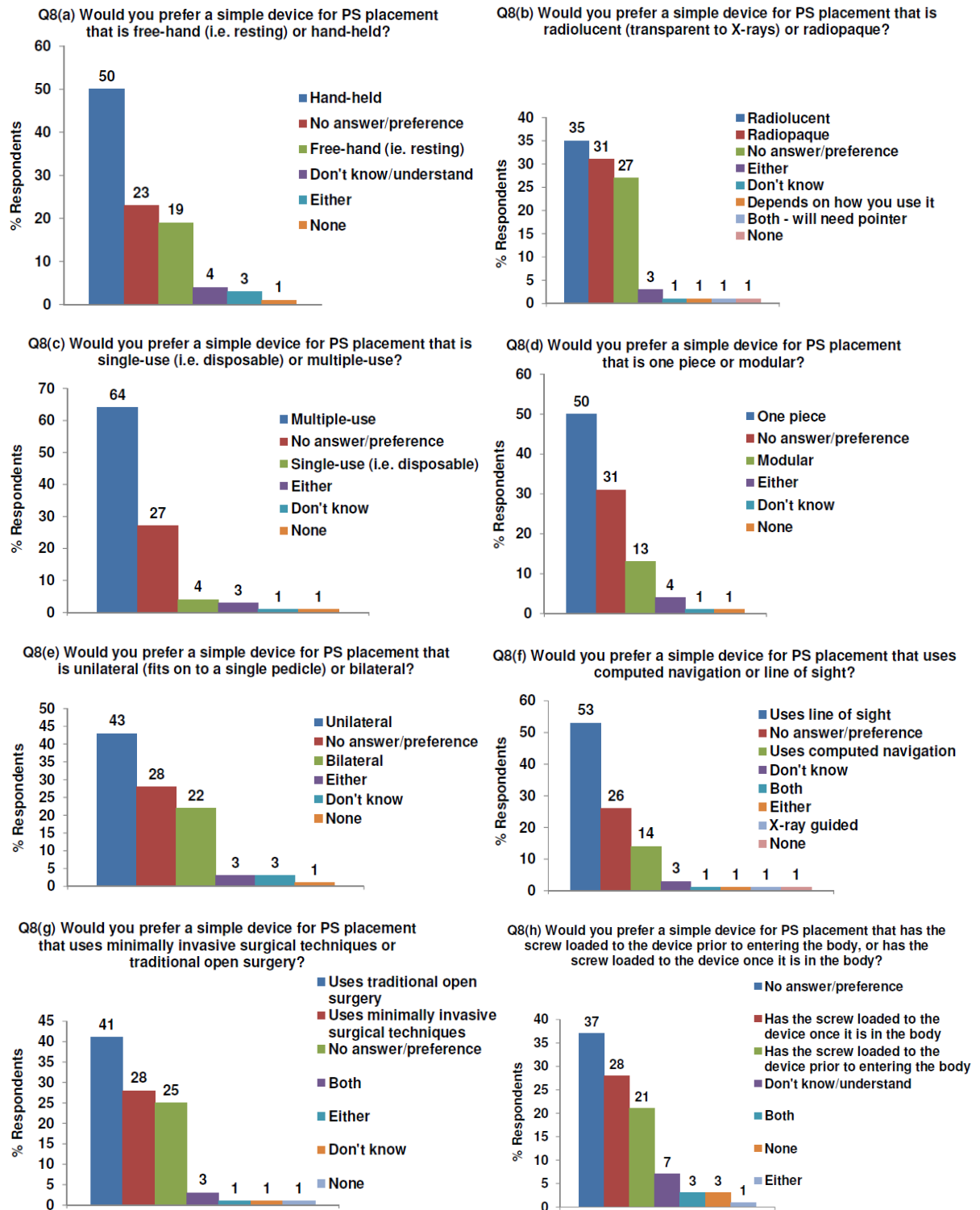


Figure 3.4 Responses to Question 8.

3.6.11 Q9. What problems, if any, have you experienced with PSs in treating patients with an OP spine?

Table 3.7 lists the problems encountered by the respondents whilst undertaking PS surgery in patients with an OP spine; these problems were already specified in the questionnaire and the respondents were asked to tick as many problems that were appropriate. Poor screw fixation, screw loosening and screw pullout after surgery was experienced by the majority of respondents. Less than half of all respondents had dealt with screw pullout during surgery, prominent/protruding hardware on the spine, screw cut-up of OP vertebrae, the requirement of revision surgery, loss of correction of the spine and problems with cement augmentation of PSs.

Table 3.7 Problems encountered by the questionnaire respondents whilst undertaking PS surgery in patients with an OP spine (Question 9).

Problem with PSs and the OP spine	Respondents (%)
Poor screw fixation/purchase	81
Screw loosening	72
Screw pullout <i>during</i> surgery	48
Screw pullout <i>after</i> surgery	58
Problems with cement augmentation of PSs	22
Loss of correction of the spine	40
Prominent/protruding hardware on the spine	45
Screw cut-up of OP vertebrae	42
Requirement of revision surgery	42
None of these problems	3
No answer at all	7

3.6.12 Q10. Historically, do you know of any screws that have been designed for OP bone? If yes, were these screws successful or unsuccessful in OP bone?

The response is shown in Figure 3.5. Respondents identified the Biomet® Omega21™ Expandable Screw design (Biomet UK Ltd., Bridgend, Wales) as being unsuccessful for fixation in OP bone and very difficult to revise. Some respondents noted the success of Ulrich Medical® articulated PSs (Ulrich GmbH & Co.KG, Ulm, Germany), when used with a greater lateral to medial insertion in OP bone. Synthes® Universal Spine System (USS) II screws were identified for their use in OP bone and USS anterior screws were noted as having

a good hold (Synthes Ltd., Welwyn Garden City, Hertfordshire, UK). In addition, respondents identified the Ulrich Medical® Tango RS™ system (Ulrich GmbH & Co.KG, Ulm, Germany), which allows screw placement with cement augmentation in OP bone. Other successful screws for OP bone included hydroxyapatite-coated screws and hollow/cannulated screws to allow cement injection. One respondent noted that another approach “is to use long Schanz screws (Willett *et al.*, 1993) to engage the anterior cortex.”

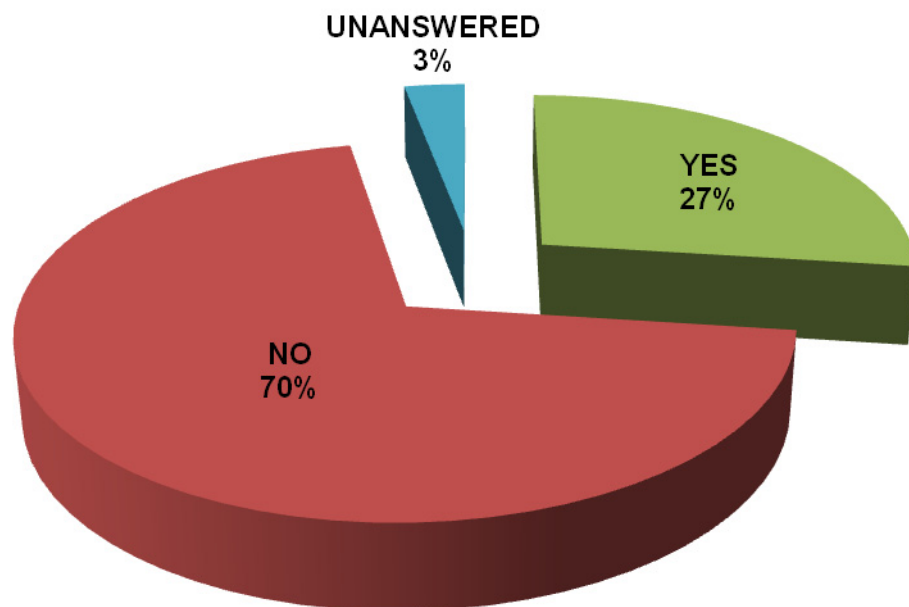


Figure 3.5 Response to Question 10: Historically, do you know of any screws that have been designed for OP bone?

Some respondents did not find screws designed for OP bone useful and thought they were very expensive and relatively unsuccessful. One respondent noted that OP bone screws are not generally used in the spine, but that locking screws in other bones had been useful.

3.6.13 Q11. Do you have any other suggestions or opinions about PSs, systems to assist spinal surgery, the design of a PS placement device or osteoporosis in the spine?

This question provided the opportunity for respondents to give any other opinions on PS surgery, which had not been previously covered in the questionnaire. Several responses consisted of statements that reinforced previous answers; these have been omitted from the following generalised list of final suggestions:

- any proposed system should secondarily, not primarily, assist stability;
- distal nail targeting devices should be considered;
- PSs may not have a long-term future.

3.7 Discussion

3.7.1 Complications Arising from PS Malpositioning

The findings suggest that the posterior-anterior approach for PS fixation is widely used. A large proportion of respondents (78%) have experienced problems with PS surgery, with several complications arising from the malpositioning of PSs (Table 3.5). The problems specified include breaching of the pedicle and vertebral body walls, pedicle fracture and various neuro-vascular impairments; many reports in the literature have documented these, and similar, complications (Boos and Webb, 1997; Esses *et al.*, 1993; Faraj and Webb, 1997; Weinstein *et al.*, 1992; West *et al.*, 1991), which is why a full literature review of clinical PS complications was not deemed necessary. Of all the problems associated with PS malpositioning, neurologic complications are generally considered the most serious. Whilst the risk of neurological deficit as a consequence of PS malposition should not be ignored, a number of studies have stated that malpositioned PSs do not lead to compromised strength or long-term neuro-vascular impairment (Schulze *et al.*, 1998; Upendra *et al.*, 2008). Respondents provide little evidence to the contrary, with only one stating “spinal cord & root damage” as a problem encountered during PS surgery; the other respondents specified no spinal cord damage or neurological deficit, despite encountering CSF leakage. It may be the case that PSs are unfairly blamed when the complications associated with them arise from other factors such as surgical technique; human error was reported as a problem with PS surgery in this questionnaire (Table 3.5). In a review of patients with PS plate fixation to the lumbar spine, Matsuzaki *et al.* (1990) noted nerve root impairment in six out of fifty-seven

patients, with all but two of the patients improving to normal status in the final analysis. Thus, there is evidence to suggest that only a minority of malpositioned PSs actually cause any severe complications.

3.7.2 Rationale for a Simple Device to Aid PS Placement

The majority of respondents (59%) think there is a need for a simple device to aid PS placement. Results show that PS surgery is particularly difficult in the cervical and thoracic spine. Only 14% of respondents have inserted screws in the cervical spine. Thus, it was not surprising that respondents were mostly in favour of a simple device to aid PS placement in the cervical and thoracic spine. Unlike the lumbar and sacral spine, the use of PSs in the cervical and thoracic spine has only become more common in recent years, as the trend towards PS instrumentation has increased to include treatment of complex spinal disorders (Nohara *et al.*, 2004). In a nationwide Japanese survey on spine surgery complications, Nohara *et al.* (2004) reported that complications occurred in the cervical (10.3%), thoracic (13.5%) and lumbar (6.7%) spine. Whilst their study included non-instrumented cases and the use of other spinal implants, PSs were used in the majority of instrumented patients (Nohara *et al.*, 2004). In their meta-analysis of PS placement accuracy, Kosmopoulos and Schizas (2007) found no advantage in using the existing navigation options in the thoracic spine, for both *in-vivo* and cadaveric populations. Along with the current study, these studies highlight the potential for a simple device to aid PS placement in the cervical and thoracic spine, with some respondents stating that a pedicle aid would encourage them to start using PSs in these regions. However, it is important to note that surgeons should first, and

foremost, rely on their anatomic and technical knowledge with regard to the accurate placement of PSs; any pedicle aid should only be considered as a supplementary tool during surgery.

Part of this questionnaire's aim was to determine the design criteria for a simple device to aid PS placement (Question 8). If the majority opinion is taken for each of the design factors in Question 8, then the overall preference was for a device that is multiple use, one-piece, hand-held, radiolucent (transparent to X-rays), unilateral (fits on to a single pedicle) pedicle aid that uses the line of sight principle in traditional open surgery, with no preference as to whether the PS should be loaded into the device before or after entering the body. In particular, over half of the respondents supported the idea of a multiple use (64%) device that uses the line of sight principle (53%). Only 14% of respondents opted for a device that uses computed navigation which, coupled with the finding that 55% of respondents do not use any spinal systems to aid PS placement, indicates that many surgeons still manually insert PSs and/or are not happy with computed navigation systems. The limitations and objections to computer-assisted image-guided navigation systems are already discussed in the literature (Grunert *et al.*, 2003; Holly, 2006; Holly and Foley, 2003).

It is interesting to note that over 20% of respondents always had no preference between the specified features in Question 8. This may suggest that Question 8 was misunderstood by some respondents and/or that it was difficult for respondents to express their desired features for a theoretical product. A similar point can be made for the 55% of respondents that stated they do not use any spinal systems to aid PS placement in Question 2; it is likely that some of

these respondents do use standard hospital equipment such as an X-ray image intensifier, given the responses to the “Other(s)” category in Question 2 (Table 3.2 and Table 3.3).

3.7.3 PSs in OP Bone

The majority of respondents experience multiple problems with PS fixation in the OP spine, notably poor purchase, loosening and pullout (Table 3.7). To address this issue, several studies have reported on the increased pullout resistance of screws augmented with polymethylmethacrylate (PMMA) and various other bone cements in OP bone (Burval *et al.*, 2007; Lotz *et al.*, 1997). However, 22% of respondents in this study still faced problems with the cement augmentation of PSs. These problems are likely to include cement leakage, neurovascular injury from exothermic reactions linked to the curing of PMMA, complications with revision surgery and hardware removal (Weinstein *et al.*, 1992; Wilkes *et al.*, 1994). This may explain why a large percentage of respondents (42%) have had to conduct revision surgery as a result of PS complications in OP bone.

Few successful screw designs appear to exist for OP bone; the majority of respondents (70%) were unfamiliar with screws specifically designed for OP bone. The reason for this could be that screw fixation is not always indicated for use in OP bone (Weinstein *et al.*, 1992). However, PS fixation to OP bone has been performed in cases of spinal instability, deformity, tumours, multi-segmental spinal stenosis (narrowing of the spinal canal) and neurological deficits that require decompression and stabilisation (Heini, 2005; Hu, 1997). As PSs increasingly gain acceptance and usage in spinal surgery, it is likely that the screws will be

used more often in OP bone, thus initiating the need for suitable screw designs. Cook *et al.* (2004) have reported positive biomechanical and clinical results with the use of Biomet® Omega21™ Expandable Screws (Biomet UK Ltd., Bridgend, Wales) for poor quality bone; they concluded that PMMA cement augmentation of the expandable PS may further improve fixation strength compared to the expandable screw alone, which has been shown to have superior fixation compared to a conventional PS. However, the responses in the current study suggest that there are some limitations to this expandable screw design. Further developments in OP bone screws include a screw augmentation technique that allows the injection of bone cement through a perforated screw (Becker *et al.*, 2008).

3.7.4 Adequate Representation of Surgeons

The 67 surgeons participating in this study were from a list of 422 surgeons provided by Surgicraft Ltd. (Redditch, UK). Whilst this list may introduce a potential selection bias, the author believes that the list accounted for the majority of surgeons known to perform spinal surgery in the UK and Ireland. The current study received a 24% response rate and 16% of the total questionnaires sent out contained useful information. The author acknowledges that a higher response rate might have resulted in a more representative group of surgeons. However, the response rate is in line with other surgical survey studies that have generated responses in the range of 22-49%, where many of these studies have used a much smaller survey group (Esses *et al.*, 1993; Glotzbecker *et al.*, 2008; Leece *et al.*, 2006).

The response rate in postal surveys is a topic of considerable investigation in the literature, because of the potential bias in the survey results from non-respondents (Harrison and Cock, 2004). There is no agreed level of acceptable response in postal surveys (Harrison and Cock, 2004); in general, the response rates are reportedly decreasing (Office for National Statistics, 2001; McAvoy and Kaner, 1996). In a national postal survey of a one in five sample of all general practitioners in England and Wales, Templeton *et al.* (1997) reported an overall response rate of 44% after four mailings to non-respondents. Clark *et al.* (2001) sent a postal questionnaire to all members of the British Society of Gynaecological Endoscopy, reporting an overall 26% response rate and no increase in the response rate when the questionnaire was printed on high quality paper instead of standard quality paper. Methods of increasing the response rate to postal surveys include writing a more personalised cover letter, using shorter questionnaires, using coloured ink, sending questionnaires by recorded delivery, contacting participants before sending questionnaires, making follow-up contact and providing non-respondents with a second copy of the questionnaire (Edwards *et al.*, 2002; Leece *et al.*, 2006); these should all be considered in any future questionnaire studies.

3.7.5 Effect of the Questionnaire Study on Subsequent Research

This study provides evidence of the potential for a simple screw positioning device in the spine, as well as a need for an improved screw for OP bone. However, the remainder of this thesis has not focused on the design of these products because Surgicraft Ltd. (Redditch, UK) did not believe that it was commercially worthwhile for them to develop the above-mentioned

products (cf. Biomet UK Ltd. experience in §A.2.7); although these products would be good subjects for future research.

The subsequent chapters have focused on other questionnaire outcomes, regarding the high incidence of poor screw purchase, screw loosening and pullout in OP bone, experienced by the majority of questionnaire respondents. Thus, in order to gain a better understanding of screw fixation in OP bone, the following work in this thesis has focused on these issues.

3.8 Conclusions

- 78% of surgeons have experienced problems with PS placement; no significant difference was found between neurosurgeons and orthopaedic surgeons.
- 55% do not use any spinal navigation systems to aid PS placement.
- PSs are mainly inserted in the thoracic, lumbar and sacral spine.
- 59% expressed a need for a simple mechanical device to aid PS placement; no significant difference was found between neurosurgeons and orthopaedic surgeons.
- Potential exists for a simple device to aid PS placement in the cervical and thoracic spine; this should only be considered as a supplementary tool during surgery.
- Surgeons would prefer a pedicle aid that is multiple use, one-piece, hand-held, radiolucent (transparent to X-rays), unilateral (fits on to a single pedicle) and that uses the line of sight principle in traditional open surgery, with no preference as to whether the PS should be loaded into the device before or after entering the body.
- Multiple problems, especially poor screw purchase, screw loosening and screw pullout, are encountered with PS fixation in the OP spine, leading to a large number of revision surgery cases; this forms the basis of the work in the remainder of this thesis.

4. COMPRESSIVE PROPERTIES OF COMMERCIALY AVAILABLE POLYURETHANE FOAMS AS MECHANICAL MODELS FOR OSTEOPOROTIC HUMAN CANCELLOUS BONE

4.1 Chapter Overview

The work reported in this chapter has already been published (Patel *et al.*, 2008). The chapter details a study that was undertaken to characterise the mechanical properties of commercially available polyurethane (PU) foams as models for osteoporotic (OP) human cancellous bone; such foams can aid in the evaluation of bone screw performance, which is discussed in the subsequent chapters. In this chapter, §4.2 introduces the study and discusses previous work by other researchers in the extensive field of cancellous bone investigation. Section 4.3 states the specific study aims. Section 4.4 describes the materials and methods used, with the results in §4.5 discussed in §4.6. The main conclusions from this study are presented in §4.7.

4.2 Introduction

4.2.1 Previous Studies on Polymer Foam Models

Little work has been carried out on synthetic materials that might mimic human OP cancellous bone. Various open-cell rigid PU foams are available for use as OP bone models because of their low material densities (typically around 0.09 g.cm^{-3}) (Sawbones® Europe AB, Malmö, Sweden). However, a literature search has revealed that few studies exist to determine whether PU foam may be a valid test material for OP cancellous bone. The following paragraphs review a number of papers that have investigated the properties of PU foams.

Szivek *et al.* (1993; 1995) measured the Young's modulus (E), compressive yield and compressive strength of three different, closed-cell, PU foam compositions (prepared during their study) for use in the study of acetabular (hip joint) subsidence. The mechanical properties of the cube-shaped PU foam specimens were found to fall within a range of cancellous bone properties from various patients; however, in their comparisons, the authors did not account for the cancellous bone properties of patients with specific diseases (Szivek *et al.*, 1995). Thus, it is difficult to determine which PU foams would be suitable in mimicking OP bone. Furthermore, it is not always efficient to formulate particular compositions of PU foam, given that there are several commercially available PU foams.

Thompson *et al.* (2003) assessed the shear and compressive properties of 0.12 g.cm^{-3} , 0.16 g.cm^{-3} , 0.20 g.cm^{-3} and 0.32 g.cm^{-3} cellular rigid closed-cell PU foam (the cell sizes ranged from 0.5 – 2 mm); these foams were deemed to be useful in simulating the elastic, but not failure, properties of cancellous bone. However, the use of 20 mm gauge diameter dumb-bell specimens under compressive axial loading raises concern over the validity of the study's conclusions; a dumb-bell shape will bias the failure of specimens towards a region of relatively high, uniform stress, which can lead to buckling (Benham *et al.*, 1996). In general, a dumb-bell specimen is not conventionally used in compression testing, where a cube or cylinder shape is favoured (Gere and Timoshenko, 1997), particularly with regard to the determination of compression properties of rigid cellular plastics (BS EN ISO 844:2009). Furthermore, in the study of Thompson *et al.* (2003), the cellular PU foams were reported as being anisotropic, with elongated cells in the foams' rise direction. Use of a 40 mm long dumb-bell shaped test geometry meant that the authors had to use a test axis perpendicular to the rise direction; this is not the preferred orientation which, in accordance with the British Standard for the compression testing of rigid cellular plastics, BS EN ISO 844:2009, would be parallel to the rise of foam. Thus, it is difficult to ascertain any reliable conclusions from this study without further testing.

Palissery *et al.* (2004) studied the static and fatigue behaviour of Herex® C70.55, a commercially available rigid, closed-cell, cross-linked polyvinyl chloride (PVC) foam, and compared it with that of cancellous bone. Dumb-bell shaped foam specimens were tested in static tension and compression. The modulus (calculated as the slope of the linear fit of the

stress-strain curves between 0.1% and 0.4% strain) and strength were greater in tension as compared to compression and the values fell within the lowest range for cancellous bone (Palissery *et al.*, 2004). In compressive fatigue, the foam (subjected to cyclic loading) exhibited qualitatively similar mechanical behaviour to cancellous bone, but the degree of modulus degradation and accumulation of permanent strain was lower than expected for cancellous bone (Palissery *et al.*, 2004). In tensile fatigue, the mechanical properties were greater than found in compression; this is opposite to the mechanical behaviour of cancellous bone (Palissery *et al.*, 2004). These authors have shown that similar static behaviour between PVC foam and cancellous bone may not predict similar fatigue behaviour (i.e. under cyclic loading). However, this study is limited by the choice of a dumb-bell test specimen shape, which will bias the results (see paragraph above), in addition to the fact that PU foams are more widely used than PVC foams as synthetic cancellous bone models (see §2.7).

In a study of sternum closure, Trumble *et al.* (2002) used 0.32 g.cm^{-3} solid rigid closed-cell PU foam as a synthetic sternum model. These authors compared two common wire closure techniques in both whole cadavers and artificial sternum models (moulded from PU foam). The magnitude of sternum separation in cadavers was found to be similar to the artificial model results at all points along the incision site for both types of sternum closure methods tested; this suggests that anatomic sternum models formed from solid rigid closed-cell PU foam can be used to approximate the biomechanical properties of cadaveric sterna. Although this study is limited by its anatomic scope, it does show that reliable information can be obtained through using bone analogue materials.

In a recent study, Johnson and Keller (2008) characterised the morphology and compressive mechanical properties (static and dynamic) of two open-cell rigid PU foams, with densities of 0.09 g.cm^{-3} and 0.12 g.cm^{-3} , as models for synthetic thoracic vertebrae; these consisted of a cylindrical open-cell foam core enclosed by a fibreglass resin cortex. The open-cell rigid foam was shown to have similar morphology and porosity as human vertebral cancellous bone (Johnson and Keller, 2008). However, this study only performed the static compression tests on 0.12 g.cm^{-3} PU foam; data for 0.09 g.cm^{-3} PU foam, one of the lowest density open-cell PU foams commercially available, is not reported. Furthermore, the authors concluded that open-cell foam provided an alternative for static or fatigue studies of human vertebrae, suggesting that future work could involve various porosity foams to simulate different degrees of OP degeneration (Johnson and Keller, 2008); but no indication is given as to which PU foam densities would act as suitable OP bone models.

The studies mentioned above have examined PU (and PVC) foams either under compression, shear or fatigue, for their use as a cancellous bone analogue material. However, none of these studies have specifically characterised PU foam as an OP cancellous bone model, by comparison of the relevant data with OP bone properties; this type of analysis is lacking in the literature and it is undoubtedly the next step toward the development of more accurate models for studying implants placed in OP cancellous bone. This requires a clear definition of the properties of cancellous bone from OP patients. The next section considers previous work by other researchers on the mechanical properties of human cancellous bone.

4.2.2 Mechanical Properties of Human Cancellous Bone

Numerous studies have characterised the mechanical properties of, predominantly normal, cancellous bone (Carter and Hayes, 1977; Gibson, 1985; Goldstein, 1987; Keller, 1994; Linde *et al.*, 1991; Martin, 1991; Morgan and Keaveny, 2001; Rice *et al.*, 1988; Rohl *et al.*, 1991); in general, the mechanical properties of cancellous bone correlate well with mineral content and apparent density (Carter and Hayes, 1977; Cowin, 1989; Weaver and Chalmers, 1966) and are moderately strain rate dependent (Carter and Hayes, 1977; Linde *et al.*, 1991). Since this chapter is concerned with modelling OP cancellous bone, the following paragraphs review the most relevant papers regarding the properties of normal and OP cancellous bone.

Nicholson *et al.* (1997) tested 48 cubic specimens, from the centre of the L4 vertebral body of 48 adult cadavers, under uni-axial compression. The specimens were from an unscreened group of subjects; no exclusions were applied for subjects with known bone disease and/or medication known to affect bone, which makes it difficult to categorise the specimens into normal and OP bone. For each cube, the authors measured E in the superior-inferior (range 44 – 368 MPa), anterior-posterior (range 5 – 122 MPa) and lateral (range 5 – 107 MPa) axes. The findings confirmed mechanical anisotropy within the vertebral body, which increased with decreasing apparent density, such that there was a relative conservation of E in the superior-inferior (axial) direction compared with the transverse directions. The authors also found an increase in E of the individual trabeculae when less bone was present (Nicholson *et al.*, 1997), providing further insight into the mechanical adaptation of vertebral cancellous bone.

Kopperdahl and Keaveny (1998) reported compressive and tensile mechanical properties for human vertebral specimens obtained from 11 cadavers; 48 cylindrical specimens that showed no radiographic evidence of bone disease were tested (the wet apparent density ranged from $0.11 - 0.27 \text{ g.cm}^{-3}$). The compressive properties determined were: E (range $90 - 536 \text{ MPa}$), yield strain (range $0.75 - 0.95\%$), ultimate strain (range $0.96 - 2.30\%$), yield stress (range $0.56 - 3.71 \text{ MPa}$) and ultimate stress ($0.70 - 4.33 \text{ MPa}$). Taking the compressive and tensile properties as a whole, E , yield stress and ultimate stress for the human vertebral bone demonstrated strong positive correlations with apparent density. However, the yield strain behaviour in compression showed a positive but weak correlation with apparent density, with the correlation being stronger in less dense bone; this suggests that the decreasing density that accompanies ageing (and osteoporosis) (Mosekilde and Danielsen, 1987) results in cancellous bone that will strain more for a given load. In contrast, the yield strain behaviour of cancellous bone in tension showed that it is a uniform failure property independent of anatomic site and apparent density.

Banse *et al.* (2002) studied the cross-linking of the collagen in cylindrical samples of human vertebral bone; specimens came from T9, T12 or L1, and L4 vertebrae from 9 donors with no relevant bone disease, thus it can be assumed that these were normal bone specimens ($n = 63$, with density values ranging from $0.09 - 0.34 \text{ g.cm}^{-3}$). The cylinders were tested under compression to determine E (range $127 - 725 \text{ MPa}$), compressive strength (range $0.60 - 6.17 \text{ MPa}$) and strain to failure (range $0.72 - 2.01\%$); the E and strength of the cylinders was highly dependent on their apparent density, whilst the strain to failure was moderately dependent (Banse *et al.*, 2002). In a rare study that investigated the nature of the extracellular matrix of human cancellous bone with mechanical testing of samples, these authors found that

the prediction of the mechanical properties was improved by combining density data with direct collagen cross-link assessment (Banse *et al.*, 2002). However, the main limitation of this study is the relatively small number of donors (9) used to collect the test specimens, which reduces the validity of the conclusions by the repeated nature of the data (the number of samples was increased by using eight samples in each spine).

Lochmüller *et al.* (2008) tested the spinal segment T11 to L1 (with target vertebra T12) as a functional unit under uni-axial compression. These units, from elderly OP cadavers, were tested to failure and the vertebral failure stress (overall mean \pm standard deviation (SD) of 2.46 ± 0.98 MPa) was correlated with quantitative computed tomography-(qCT)-based bone density. Compared to the cancellous bone density (overall mean \pm SD, 0.08 ± 0.04 g.cm⁻³), the cortical density (overall mean \pm SD, 0.25 ± 0.07 g.cm⁻³) of T12 was more strongly correlated with the vertebral failure stress, thus emphasising the importance of the cortical shell in warranting mechanical integrity of the vertebral body (Bryce *et al.*, 1995). Using micro-computed tomography (μ CT) on 6 mm cylindrical bone biopsies, Lochmüller *et al.* (2008) also studied the cancellous bone microstructure of T10 and L2 vertebrae from 165 elderly OP donors; no significant differences were found in the microstructural properties between T10 and L2, nor were there any gender differences. However, the study (Lochmüller *et al.*, 2008) did not use normal bone control specimens with which to compare the OP specimens by and the mechanical properties of the bone biopsies are not reported.

Nazarian *et al.* (2008) imaged normal, OP, and metastatic cancer cancellous bone using μ CT and then mechanically tested these specimens under uni-axial compression. Of particular note

was the use of a mechanical testing and data acquisition device (Nazarian and Muller, 2004; Nazarian *et al.*, 2005) that incorporated stepwise axial compression in combination with time-lapsed μ CT imaging to study the three-dimensional (3D) failure behaviour of cellular solids (Muller *et al.*, 1998). The least rigid segment(s) of the specimen, where the most deformation occurred, was found at the sub-region with the minimum bone volume fraction (BV/TV) and this region governed most (approximately 84%) of the mechanical behaviour of the entire specimen (Nazarian *et al.*, 2008). Forty-one cylindrical cancer specimens and 96 non-cancer specimens (these were divided between 61 normal and 35 OP specimens using bone mineral density measurements) were obtained from the spine or proximal femur (thigh bone); average BV/TV of the OP specimens was 31% lower than that of the normal specimens and not different from that of the cancer specimens (Nazarian *et al.*, 2008). For normal and OP specimens respectively, the mean \pm SD for E was reported as 356 ± 90 MPa and 190 ± 95 MPa, whilst the respective yield strength was reported as 101 ± 22 MPa and 41 ± 22 MPa. The cancer specimens had a slightly higher E but similar yield strength to the OP specimens (Nazarian *et al.*, 2008).

The spine and proximal femur are both high-risk sites that can be subject to osteoporosis-induced fracture (Dequeker *et al.*, 1994). Consequently, a number of studies have also focused on the mechanical properties of femoral cancellous bone. Changes in the cancellous bone of femoral heads (at the proximal end of the thigh bone) have been reported in osteoporosis (Bailey *et al.*, 1992) and osteoarthritis (Mansell and Bailey, 1998) and the bone has been reported to be weaker than normal bone (Li and Aspden, 1997).

The work of Li and Aspden (1997) is one of the few studies (Brown *et al.*, 1981; Deligianni *et al.*, 1991; Sun *et al.*, 2008) found to measure bone properties of femoral heads through biomechanical methods; it is also advantageous in that these authors (Li and Aspden, 1997) used normal bone controls in their study of OP and osteoarthritic (OA) cancellous bone. Compression tests were performed on 7 normal, 16 OA and 17 OP femoral heads by taking cylindrical bone cores from the superior, inferior, anterior, posterior, medial, lateral and central regions of each femoral head (Li and Aspden, 1997). Normal cancellous bone was sourced from hips removed during post mortem examination; the medical records were examined to exclude disorders affecting bone metabolism. OA cancellous bone was obtained from patients undergoing a hip replacement for osteoarthritis of the hip, whilst the OP cancellous bone was sourced from patients undergoing a hip replacement for a fractured neck of femur attributed to osteoporosis. Femoral heads from all three clinical groups were matched for age and gender. E (OA bone median 356 MPa; normal bone median 310 MPa; OP bone median 247 MPa), yield strength (OA bone median 4.3 MPa; normal bone median 3.3 MPa; OP bone median 2.5 MPa) and energy absorbed to yield (OA bone median 31.9 kJ.m⁻³; normal bone median 21.8 kJ.m⁻³; OP bone median 16.3 kJ.m⁻³) were determined. Li and Aspden's (1997) investigation showed that the apparent density and mechanical stiffness of cancellous bone from the femoral head are increased in osteoarthritis and decreased in osteoporosis compared with normal, which is in agreement with previous studies (Deligianni *et al.*, 1991). The normal and OP bone were also found to have very similar stiffness-density relationships and composition, which supports the concept that osteoporosis is a loss of normal bone (Lane and Nydick, 1999; Li and Aspden, 1997; Riggs and Melton, 1986).

The studies mentioned in this section provide information on the mechanical properties of cancellous bone and their relationships with density and microstructure. What is less clear is the relationship between the mechanical properties of normal and OP cancellous bone, which has not always been studied in an inclusive manner. The current study stemmed from the lack of data on PU foams that could mimic OP bone; in part, this is due to the difficulty in obtaining a reliable and representative data set for normal and OP bone. No previous study has compared the mechanical properties of PU foams with results from a study of normal and OP human bone using exactly the same mechanical test methods. Thus, it was decided that the current study would be based on Li and Aspden's study on the compressive mechanical properties of cancellous bone (1997); their study was chosen for several important reasons. Firstly, Li and Aspden used samples from seven defined sites in normal and OP femoral heads, which were subjected to different loads *in-vivo*; such a wide range of loading conditions provides a useful foundation upon which to model OP bone. Furthermore, Kanis *et al.* (2008) recently suggested that a reference standard for reporting osteoporosis should be based on measurements at the femoral neck; this is very close to the femoral head area considered by Li and Aspden. Secondly, the straightforward manner of Li and Aspden's compression testing and data analysis methods allowed for these to be easily replicated in the present study. Thirdly, Li and Aspden compared OP bone with normal bone and the results were found to support the current concept that OP bone material is normal in quality but reduced in quantity (Lane and Nydick, 1999; Riggs and Melton, 1986); for the current study, this helped to determine the suitability of different density PU foams as models for OP and normal bone. Fourthly, Li and Aspden tested human cancellous bone specimens, obtained in theatre from patients undergoing a hip replacement, which provided a valid set of bone samples to model with PU foam.

4.3 Purpose of the Investigation

In this chapter, the aim was to determine whether any low density PU foam (i.e. open-cell or closed-cell) might be suitable as a mechanical model for human OP bone. Suitability was determined by measuring the E , yield strength and energy absorbed to yield for three PU foams and directly comparing them with the corresponding values obtained from a study of human OP cancellous bone (Li and Aspden, 1997). The determination of such mechanical properties may help selection of the relevant PU foams as an OP cancellous bone model in other studies; for example, in the mechanical evaluation of implant performance (Sommers *et al.*, 2007).

4.4 Materials and Methods

4.4.1 PU Foam Samples

PU foams, of three different densities, were used in this study (Figure 4.1). Closed-cell PU foam of density 0.16 g.cm^{-3} and 0.32 g.cm^{-3} (American Society for Testing and Materials, ASTM, Grade 10 and Grade 20) (ASTM F1839-08, 2008) was used to model low and medium density cancellous bone, respectively. Open-cell rigid foam of density 0.09 g.cm^{-3} was used to model very low density cancellous bone. All PU foams were purchased in block

form, with dimensions $130 \times 180 \times 40$ mm, from Sawbones® Europe AB, Malmö, Sweden. The foam densities were supplied by Sawbones® Europe AB.



Figure 4.1 The three rigid PU foams, of different densities, used in this compression study.

Using a sharpened tube, six cylindrical cores of 9 mm diameter were drilled from each of the three different density PU foam blocks. The cores were cut parallel to the PU foam rise direction (i.e. perpendicular to the top surface of the block) so as to mimic the approach by Li and Aspden (1997) in their study of femoral cancellous bone; their cores were taken with the cylindrical axis along the preferred orientation of the trabeculae, which, at the surface, is also approximately perpendicular to the surface (Li and Aspden, 1997). The exact diameter of the PU cylinders was determined as an average of four measurements; this was necessary to account for the inhomogeneity of the 0.09 g.cm^{-3} open-cell PU foam in particular.

In view of the delicate, cellular structure of the PU foams (Figure 4.1), it was decided that E , the yield strength and the energy absorbed to yield would be measured in compression; this is easier to perform than other forms of testing, such as tension tests. Furthermore, compression testing of the PU foams enabled a direct comparison of mechanical properties with those obtained from a compression study of human OP cancellous bone (Li and Aspden, 1997).

For this study, two different cylinder lengths were chosen to test for any buckling or shape effects. A cylinder, of length 7.7 ± 0.2 mm, was chosen so that results could be compared with those from a published study of human OP cancellous bone (Li and Aspden, 1997). In order to investigate the effect of specimen dimensions, a cylinder, of length 3.9 ± 0.1 mm, was also investigated. This length was calculated from an aspect ratio obtained from a standard for testing rubbers (BS 903-A6:1992), based on the standard's "Type A" cylindrical test piece of 29 mm diameter and 12.5 mm length. The following calculations were made:

$$\text{Aspect ratio} = \frac{\text{width}}{\text{height}} = \frac{29 \text{ mm}}{12.5 \text{ mm}} = 2.32$$

A 9 mm cylinder width with a 2.32 aspect ratio gives a required cylinder height of:

$$\frac{9}{\text{height}} = 2.32 \quad \Rightarrow \quad \text{height} = 3.9 \text{ mm}$$

The reason for choosing this standard was to ensure that the specimens did not bulge during compression; rubbers have a Poisson's value of about 0.5 and so maintain an almost constant volume during compression; as a result, they bulge more than most other materials (O'Sullivan *et al.*, 2003; Widdle Jr *et al.*, 2008). Dimensions were measured along the

cylinder length with digital vernier callipers (Fisher Scientific UK Ltd., Loughborough, Leicestershire, UK).

Six cylinders were prepared for each cylinder length and each density of PU foam block. The required cylinder length was achieved by either using a small pair of scissors, for the 0.09 g.cm^{-3} PU foam, or by rubbing the PU foam cylinder on a sheet of sandpaper (medium grade M2, SupaDec, RS Components Ltd., Northamptonshire, UK), for the 0.16 g.cm^{-3} and 0.32 g.cm^{-3} PU foams.

4.4.1.1 Factors Affecting the Outcome of Compression Tests

At this stage, it is important to note several factors that could affect the outcome of this compression study. With regard to short cylinder test specimens under compression, the specimen aspect ratio (height to diameter) will influence the amount of interaction between shear strain fields in the material (Dieter, 1988). Shear strain fields arise from frictional resistance in the part of the specimen in contact with the compression plates, leading to a barreled specimen profile (Figure 4.2). Internally, a region of non-deformed material is created near the compression plate surfaces (Figure 4.2). As these cone-shaped zones approach and overlap, they cause an increase in force for a given increment of deformation (Dieter, 1988). So for a fixed diameter, a shorter cylinder will require a larger axial force to produce the same percentage reduction in height because of the relatively larger non-deformed region (Figure 4.2). To minimise such barreling and non-uniform deformation, a low aspect ratio (a) of approximately 1.5 can be used (Cottrell, 1975), where a = initial

cylinder height (h_0) / initial cylinder diameter (D_0). In the current study, $a = 0.4$ and $a = 0.9$ for the 3.9 mm and 7.7 mm length PU cylinders, respectively. Because this study was designed to replicate the exact same testing methodology of Li and Aspden (1997), the constraints placed on their own specimen sampling (cylinders of mean length 7.7 mm and 9 mm diameter were extracted from seven different sites of each femoral head) (Li and Aspden, 1997) meant that the PU foam specimen size and shape had to be compromised in the current study. Thus, it is likely that the PU foam specimens, particularly the 3.9 mm length cylinders, would have been influenced by the frictional end-effect and shear strain field collision behaviour described here (Figure 4.2).

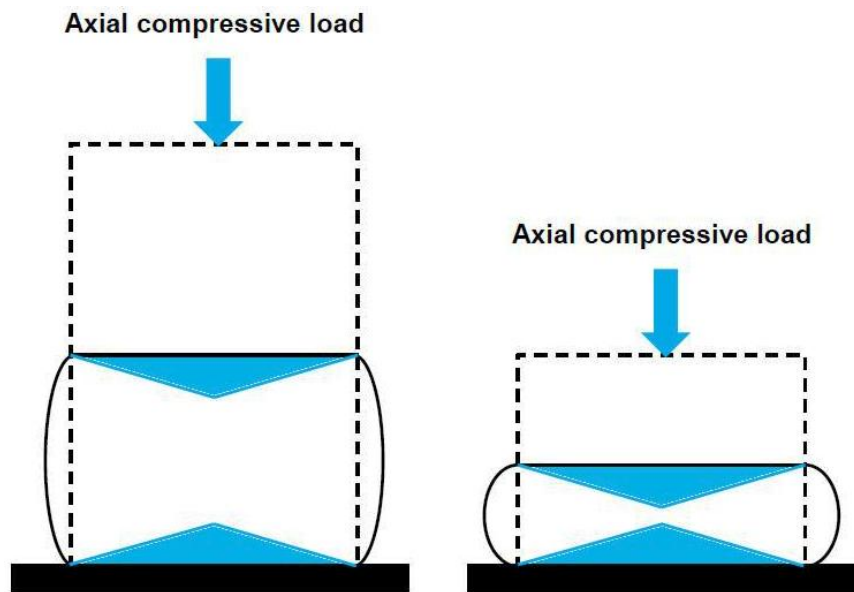


Figure 4.2 Friction at the ends of a cylindrical compression specimen will cause barreling and shear strain fields, arising from non-deformed regions (blue cones); this is more of a problem in shorter cylinders of the same diameter because of the interaction between shear strain fields (*right*) (based on Figure 15-11 in Dieter, 1988).

The compression of cancellous bone specimens, as performed by Li and Aspden (1997), will also be influenced by the exposed trabeculae, i.e. trabecular damage at all cut ends of the

specimen and the trabeculae free ends in contact with the compression plates; these “end-artifacts” can lead to testing errors (Keaveny *et al.*, 1993a; Linde and Hvid, 1989; Linde *et al.*, 1992; Odgaard and Linde, 1991; Zhu *et al.*, 1994). To remove trabecular end-artifacts, Keaveny *et al.* (1997) proposed an end-cap technique for cancellous bone compression, whereby highly porous bone specimens were gripped into aligned brass end-caps. This technique has reduced the underestimation errors in modulus measurement (Keaveny *et al.*, 1997), which were in the range of 20-40% when standard compression plate testing was used (Keaveny *et al.*, 1997; Odgaard and Linde, 1991); consequently, the end-cap technique has been adopted by several researchers (Banse *et al.*, 2002; Nazarian *et al.*, 2008). However, the end-cap technique raises uncertainty in the specimen test length since the load measurements would incorporate both the bone between the end-caps and some unknown portion of the bone within the end-caps. Furthermore, the end-cap technique is limited by the requirement of a relatively large test specimen, where the overall specimen length is typically four times the specimen diameter (Keaveny *et al.*, 1997). Thus, the end-cap technique is not applicable to the current study, where small PU foam cylinders (see §4.4.1) have been used to match the specimen size used by Li and Aspden (1997). In addition, the results from the current study were intended to be compared with those of Li and Aspden (1997), who also did not use end-caps in their compression tests of human cancellous bone, which is why the end-cap technique has not been used here.

Another factor influencing cancellous bone compression is the presence of “side-artifacts”; these arise from the sides of the specimen where peripheral trabeculae lose their vertical load-bearing capacity due to interruption of connectivity (Un *et al.*, 2006; Zhu *et al.*, 1994). Side-artifacts are unavoidable with cancellous bone specimens; but they do depend on trabecular

spacing (or cell size in PU foams) (Andrews *et al.*, 2001; Bevill *et al.*, 2007; Onck *et al.*, 2001; Ün *et al.*, 2006), and can result in underestimation of elastic modulus by as much as 50% in human vertebral bone (Ün *et al.*, 2006). In the present study, this places importance on the number of “trabecular” repetitions within each test specimen, particularly for the 0.09 g.cm^{-3} open-cell PU foam samples, because a large enough PU foam core is required to be free of the influence of side-artifacts and yet be representative of the test material. Ün *et al.* (2006) found that the side-artifact represents a layer of peripheral trabeculae that is approximately 0.2 - 0.6 mm wide, depending in part on the mean trabecular separation. Therefore, the 9 mm diameter PU foam cylinders in this study may only be representative of a true 7.8 mm synthetic bone core, if the region influenced by side-artifacts is excluded. Subsequently, the number of “trabecular” repetitions in the 0.09 g.cm^{-3} PU foam cylinders can be calculated, using the known cell size range of 1.5 – 2.5 mm (Sawbones® Europe AB, Malmö, Sweden), as an approximate range of 3 – 5 “trabecular” repetitions. For the 0.16 g.cm^{-3} and 0.32 g.cm^{-3} PU foams, it is difficult to calculate the possible number of “trabecular” repetitions, due to the 95 – 99.9 % closed-cell content of these solid PU foams (Sawbones® Europe AB, Malmö, Sweden).

4.4.2 Mechanical Testing

Quasi-static unconstrained compression tests (Figure 4.3) were conducted using an ELF3200 (for the lowest density foam) or an ELF3300 (for other PU foams) materials testing machine (Bose Corporation, ElectroForce Systems Group, Minnetonka, MN, USA).

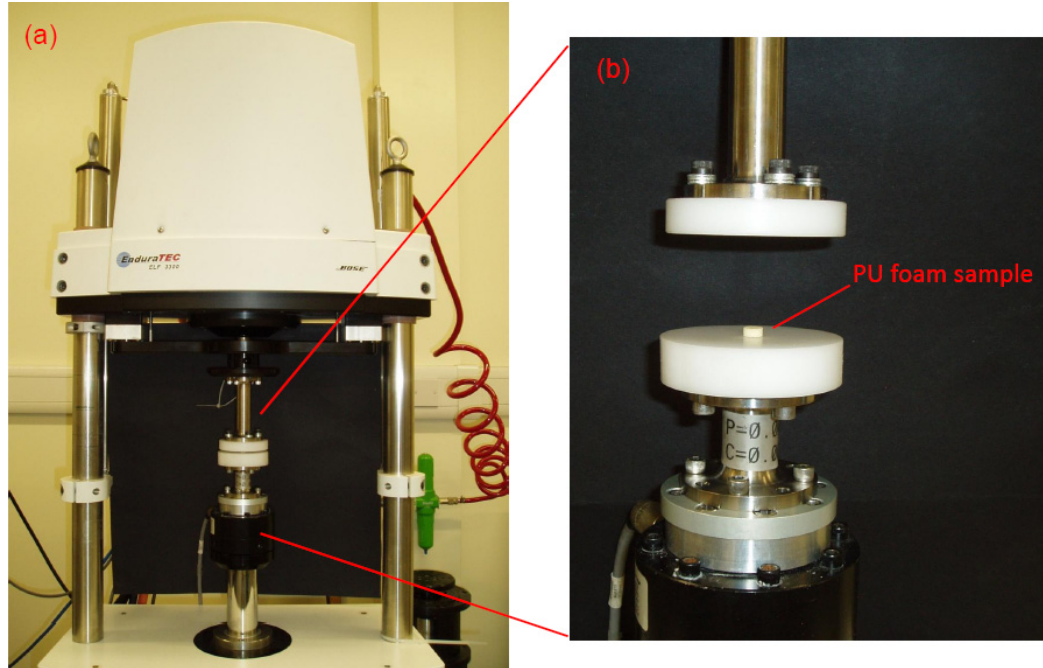


Figure 4.3 PU foam compression test set-up using the (a) ELF3300 materials testing machine, with (b) a close-up of a PU foam cylinder sample that was compressed between two acetal plates.

The lowest density foam was tested using a different machine, with a lower capacity load cell, because of its greater compliance and lower strength. All tests were video-recorded using a video camera (Sony Handycam DCR-DVD404E, Sony Corporation, Japan). No preload or preconditioning was applied to the specimens, which were compressed between two acetal plates (each of 80 mm diameter and 15 mm thickness, manufactured from RS Acetal Plastic Rod Stock # 438-6235, RS Components Ltd., Northamptonshire, UK). For the 3.9 mm and 7.7 mm cylinder lengths, tests were performed under displacement control at a rate of 0.013 mm.s^{-1} and 0.026 mm.s^{-1} respectively, both of which are equivalent to a strain rate of 0.0033 s^{-1} (Li and Aspdén, 1997).

To fully replicate the testing method of Li and Aspden (1997), no lubricant was used between the PU specimen and compression plate interfaces; this could cause frictional effects, as discussed in §4.4.1.1. Acetal compression plates were chosen because they were readily available at the time of testing. During compression, the displacement of each acetal plate was negligible when compared to the displacement of each PU foam sample. For a 0.32 g.cm^{-3} PU foam cylinder of 7.7 mm length (the densest foam tested), with the largest E value obtained in this study (151 MPa), the displacement was recorded as 0.17 mm, whilst the displacement of each acetal plate was calculated as only 0.0001 mm.

4.4.3 Data Analysis

For each compression test, the engineering stress was calculated by dividing the load recorded at each data point by the original cross-sectional area of the PU foam cylinder, whilst the engineering strain was calculated by dividing the displacement of the machine actuator head (at each data point) by the original height of the PU foam cylinder (Turner and Burr, 1993). A fifth-order polynomial was fitted to the stress-strain curves, which provided the best approximation of the shape of the stress-strain curves, to give the following general relationship:

$$\sigma = p\varepsilon^5 \pm q\varepsilon^4 \pm r\varepsilon^3 \pm s\varepsilon^2 \pm t\varepsilon \pm u \quad (4.1)$$

where σ is the engineering stress; ε is the engineering strain and p , q , r , s , t , and u are coefficients that give the least-squares best fit to the experimental results.

The mechanical properties determined were E , the yield strength, and the energy absorbed up to the yield point. A general expression for the gradient of the stress-strain curve was found by differentiating equation 4.1 with respect to strain, such that:

$$\frac{d\sigma}{d\varepsilon} = 5p\varepsilon^4 \pm 4q\varepsilon^3 \pm 3r\varepsilon^2 \pm 2s\varepsilon \pm t \quad (4.2)$$

In this study, E was determined graphically, i.e. as the first maxima value when $d^2\sigma/d\varepsilon^2 = 0$ (see Figure 4.4b). The same approach was used in Li and Aspden's study (1997), with which the current study results were compared.

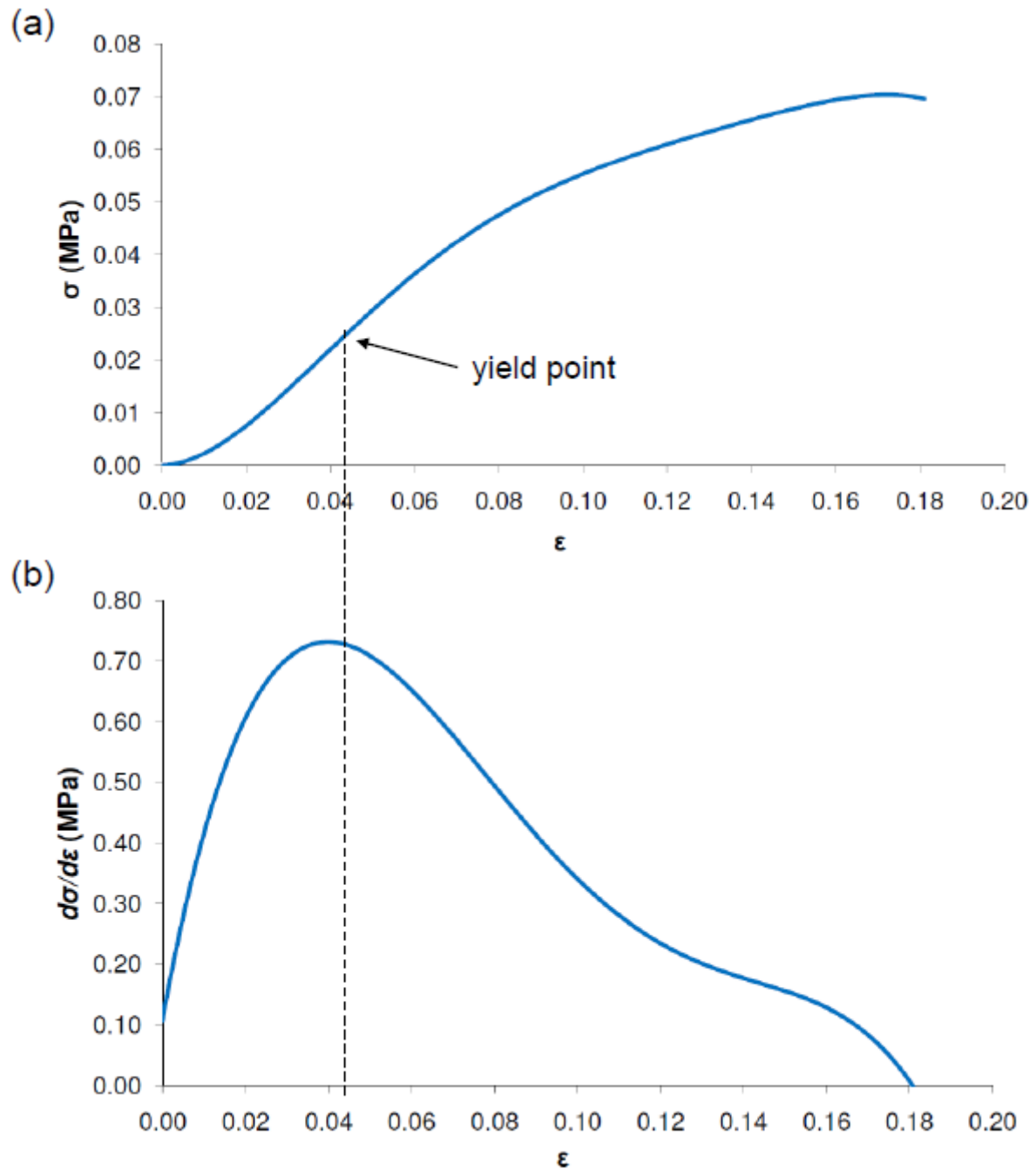


Figure 4.4 (a) Typical stress (σ) versus strain (ϵ) curve from a 7.7 mm length sample of open-cell PU foam (0.09 g.cm^{-3}) used to model very low density human cancellous bone and (b) the gradient of the σ versus ϵ curve ($d\sigma/d\epsilon$) plotted against ϵ . The yield point is defined by the point at which $d\sigma/d\epsilon$ decreases by 3% from its first maxima value.

The yield strength was determined by the method described by Li and Aspden (1997) as the stress at which E had reduced by 3% from its maximum value (Figure 4.4); this provided a useful comparison with normal and OP cancellous bone (Li and Aspden, 1997). The energy absorbed to yield, per unit volume of material, was calculated by integrating equation 4.1, with respect to strain, between the limits of zero and the strain point at which the yield strength was determined (Figure 4.4), such that:

$$\text{Energy absorbed to yield} = \int_0^{\varepsilon \text{ at yield point}} \sigma d\varepsilon \quad (4.3)$$

All of the above data analysis methods were justified because they enabled a direct comparison with the results of Li and Aspden (1997). Microsoft Office Excel (2003 version, Microsoft Corporation, Redmond, Washington, USA) was used to perform the data analyses.

4.4.4 Statistical Analysis

Statistical calculations were performed using MINITAB® Release 14.1 Statistical Software (Minitab Inc., Pennsylvania, USA). Normality of the distributions was assessed using the Anderson-Darling test (Bland, 2000). Data were compared using the two-sample t-test (normally distributed data) or the Mann-Whitney test (non-parametric data), with the significance level set at 0.05 for all tests.

4.5 Results

Table 4.1 summarises the differences in values for E , yield strength and energy absorbed to yield between the 3.9 mm and 7.7 mm length PU foam cylinders. Significant differences were detected in E between 3.9 mm and 7.7 mm length PU foam cylinders for all three PU foam densities ($p < 0.05$). No significant differences were detected in the yield strength between 3.9 mm and 7.7 mm length PU foam cylinders for all three PU foam densities. For the energy absorbed to yield, significant differences ($p < 0.05$) were detected between 3.9 mm and 7.7 mm length PU foam cylinders for 0.16 g.cm^{-3} and 0.32 g.cm^{-3} PU foams, but not for the 0.09 g.cm^{-3} PU foam.

Table 4.1 Young's modulus (E), yield strength and energy absorbed to yield for PU foam cylinders under compression. Values are shown as the mean (of six data points) \pm standard deviation.

9 mm diameter PU foam cylinder	E (MPa)	Yield strength (MPa)	Energy absorbed to yield (J.m ⁻³)
<i>0.09 g.cm⁻³ density foam</i>			
3.9 mm length	0.3 ± 0.2	0.02 ± 0.01	0.8 ± 0.6
7.7 mm length	0.7 ± 0.2	0.04 ± 0.02	1.5 ± 1.4
<i>0.16 g.cm⁻³ density foam</i>			
3.9 mm length	19 ± 3	1.0 ± 0.1	27.3 ± 10.0
7.7 mm length	41 ± 3	1.1 ± 0.1	10.6 ± 2.7
<i>0.32 g.cm⁻³ density foam</i>			
3.9 mm length	66 ± 13	3.6 ± 0.5	96.6 ± 47.9
7.7 mm length	145 ± 6	3.3 ± 0.9	26.5 ± 14.4

Figures 4.5 – 4.7 compare the median values for E (Figure 4.5), yield strength (Figure 4.6) and energy absorbed to yield (Figure 4.7), obtained from this study, with the corresponding values found from Li and Aspden's study that investigated the mechanical properties of human OP and normal bone (1997). In particular, a direct comparison can be made between the 7.7 mm PU cylinder length and the results of Li and Aspden (1997) because of the matched specimen size. Median values are reported in Figures 4.5 – 4.7 because not all of Li and Aspden's data were normally distributed; the median is the numeric value separating the higher half of the sample from the lower half, and when there is no single middle value for the

ordered observations (from lowest to highest) then the median is defined as the mean of the two middle values (Bland, 2000). Figures 4.5 – 4.7 include ranges of the 5% to 95% confidence limits from Li & Aspden's study; these ranges were extracted from box plots and are only approximate values.

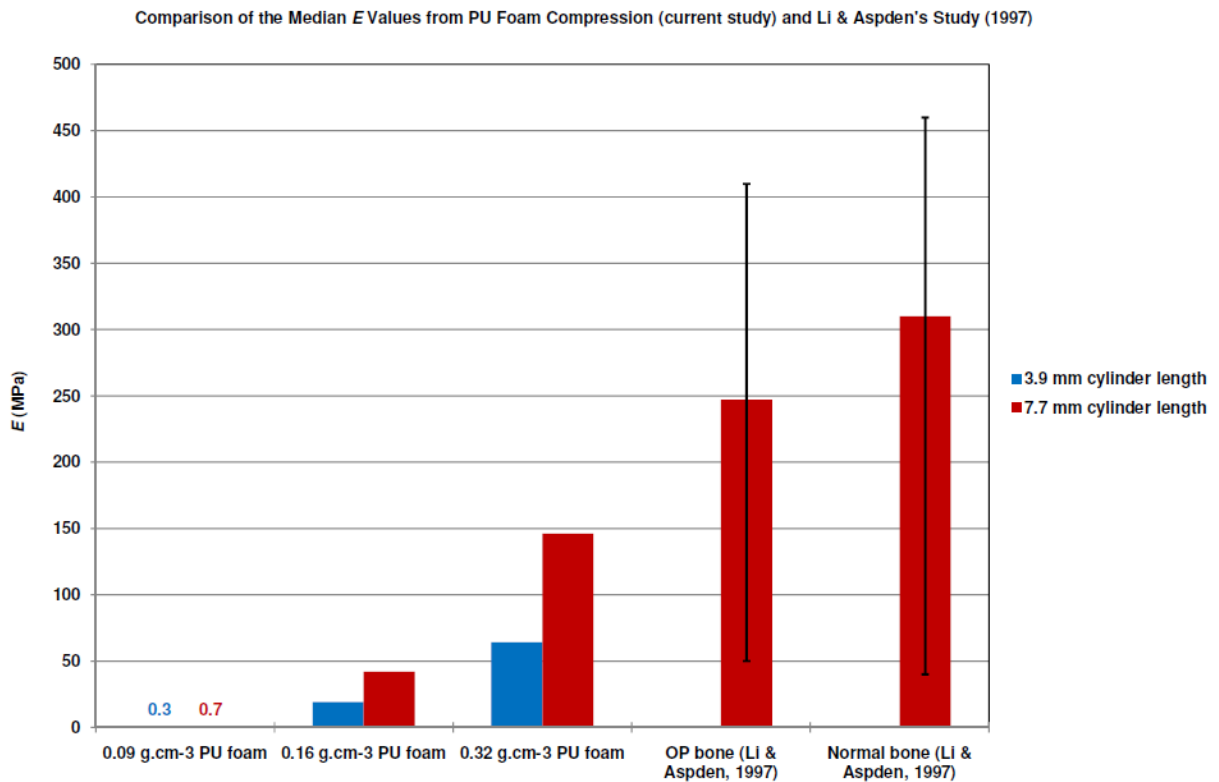


Figure 4.5 Bar chart comparing the median values for E with Li & Aspden's study (1997) on the mechanical properties of human cancellous bone specimens (diameter: 9 mm, mean cylinder length: 7.7 mm) from OP and normal femoral heads. The error bars represent approximate ranges of the 5% - 95% confidence limits from Li & Aspden's study (1997). E for the 0.09 g.cm⁻³ open-cell PU foam is explicitly shown because of the relatively small values that were found.

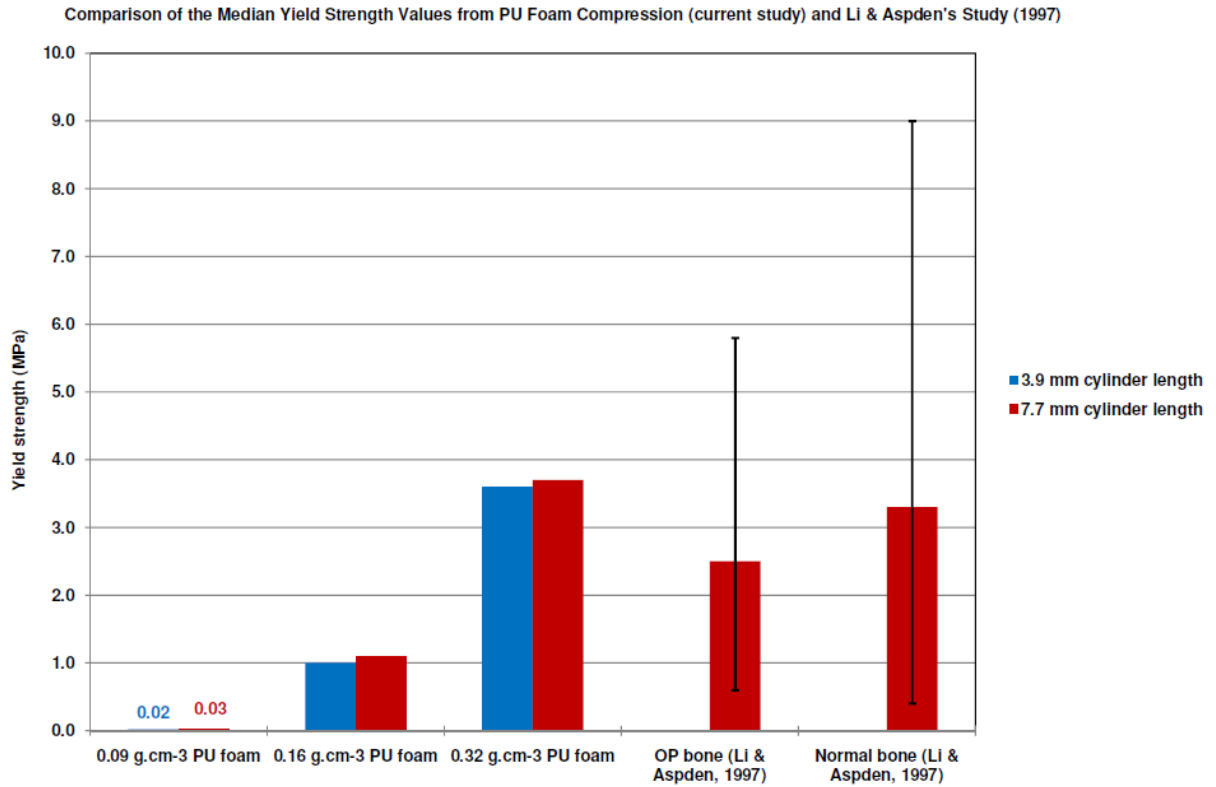


Figure 4.6 Bar chart comparing the median values for yield strength with Li & Aspden's study (1997) on the mechanical properties of human cancellous bone specimens (diameter: 9 mm, mean cylinder length: 7.7 mm) from OP and normal femoral heads. The error bars represent approximate ranges of the 5% - 95% confidence limits from Li & Aspden's study (1997). The yield strength for the 0.09 g.cm⁻³ open-cell PU foam is explicitly shown because of the relatively small values that were found.

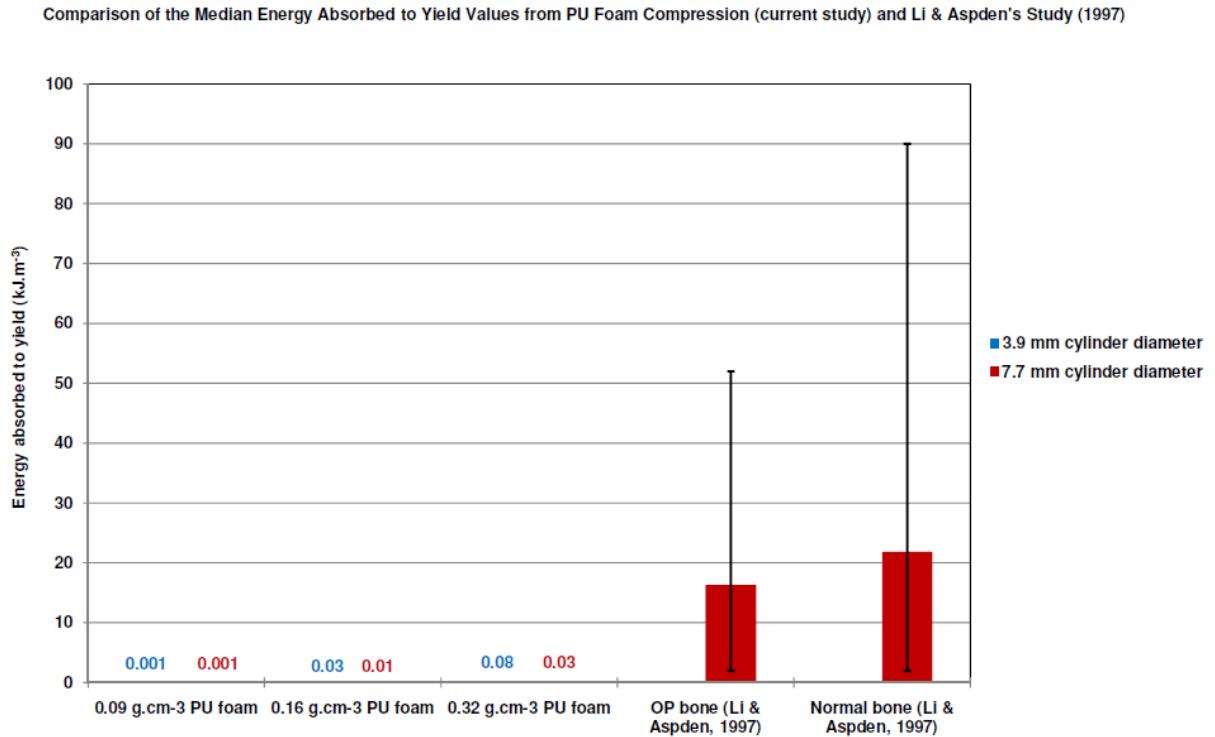


Figure 4.7 Bar chart comparing the median values for energy absorbed to yield with Li & Aspden's study (1997) on the mechanical properties of human cancellous bone specimens (diameter: 9 mm, mean cylinder length: 7.7 mm) from OP and normal femoral heads. The error bars represent approximate ranges of the 5% - 95% confidence limits from Li & Aspden's study (1997). The energy absorbed to yield for all PU foams tested in the present study are explicitly shown because of the relatively small values that were found.

Inspection of video recordings showed a repetitive cycle of “trabeculae” fracture and consolidation during compression (particularly for the 0.09 g.cm⁻³ PU foam). All test cylinders experienced loads less than the critical load required for Euler buckling (see Appendix D for these calculations) and no such buckling was observed in the video images.

4.6 Discussion

The purpose of this work was to determine whether any low density PU foam (open-cell or closed-cell) might be suitable as a mechanical model for human OP cancellous bone. To the author's knowledge, this is the only study to date that has compared the mechanical properties of PU foams with results from human bone (Li and Aspden, 1997) using exactly the same mechanical test methods. The study results provide evidence that at least one out of the three foams tested can be a model for OP bone; this is relevant for the testing of bone screws in the subsequent chapters. The results for each density of PU foam are discussed in the following paragraphs.

The 0.09 g.cm^{-3} PU foam, used to model very low density bone in this study, is much weaker than the OP bone investigated by Li and Aspden (1997). Table 4.1 and Figures 4.5 – 4.7 show that values of E , yield strength and energy absorbed to yield, for the 0.09 g.cm^{-3} PU foam, are below the range (based on the 5% and 95% confidence limits) of Li and Aspden's results. These findings may highlight a difficulty in using open-cell PU foam to model OP cancellous bone. The problems associated with modelling OP bone are discussed later in this section.

For the 0.16 g.cm^{-3} and 0.32 g.cm^{-3} PU foams used in this study, the range of E and yield strength was 15.1 - 151.4 MPa and 0.9 - 4.5 MPa, respectively. For human cancellous bone, the literature has reported E to vary within the range of 1.1 – 9800 MPa (Goldstein, 1987;

Jutley *et al.*, 2002; Rohl *et al.*, 1991), which includes human cancellous bone located across the tibia, vertebral bodies and humerus, whilst the yield strength is reported to differ within the range of 0.6 - 17.5 MPa (Kopperdahl and Keaveny, 1998; Morgan and Keaveny, 2001), accounting for cancellous bone within the vertebra, tibia and femur. Results for the 0.16 g.cm⁻³ and 0.32 g.cm⁻³ PU foam used in this study are within these ranges quoted above; this agreement is to be expected because foams with this density are intended to meet the ASTM F1839-08 standard. However, use of 0.32 g.cm⁻³ PU foam as a “normal” bone model can be justified to a greater extent than the 0.16 g.cm⁻³ PU foam; the 0.32 g.cm⁻³ PU foam gave similar values for E (i.e. they fell within the 5% and 95% confidence limits of Li and Aspden’s results) and yield strength between this study and Li and Aspden’s work (1997) on normal bone (Figure 4.5 and Figure 4.6).

It is difficult to categorise the 0.16 g.cm⁻³ PU foam as a “normal” or OP bone model. E values for the 0.16 g.cm⁻³ foam are close to the 5% confidence limits of 40 and 50 MPa for normal and OP bone respectively (Li and Aspden, 1997) (Figure 4.5). In addition, yield strength values for the 0.16 g.cm⁻³ foam are close to the 5% confidence limits of 0.4 and 0.6 MPa for normal and OP bone respectively (Li and Aspden, 1997) (Figure 4.6). These findings suggest that, based on the 5% confidence limits for E and yield strength found by Li and Aspden (1997), the 0.16 g.cm⁻³ PU foam may prove suitable as an OP bone model for mechanical testing that is concerned with fracture stress.

The PU foams tested in this study were all obtained from Sawbones® Europe AB, Malmö, Sweden. The least dense open-cell foam, 0.09 g.cm⁻³, featured as a substitute for OP bone on

the Sawbones® website, has been used in the current study because there is no evidence from Sawbones® that it is a suitable material for OP bone. The Sawbones® website quotes larger values for the compressive modulus (6.2 MPa, 0.09 g.cm⁻³; 58 MPa, 0.16 g.cm⁻³; 210 MPa, 0.32 g.cm⁻³) and compressive strength (0.11 MPa, 0.09 g.cm⁻³; 2.2 MPa, 0.16 g.cm⁻³; 8.4 MPa, 0.32 g.cm⁻³) compared to those obtained in this study; data regarding the energy absorbed to yield are not provided by Sawbones®. The method used to determine the material property data for 0.09 g.cm⁻³ open-cell PU foam is not provided by Sawbones®; however, for the 0.16 g.cm⁻³ and 0.32 g.cm⁻³ closed-cell PU foams, Sawbones® state that the data were obtained parallel to the rise of foam using a standard test method for compressive properties of rigid cellular plastics (ASTM D1621-04, 2004). This standard uses a test specimen with a square or circular cross-section, with a minimum height of 25.4 mm and a maximum height no greater than the width or diameter of the specimen (ASTM D1621-04, 2004). Thus, the marked difference in test specimen geometries used by Sawbones® and the present study helps to explain the difference between the two sets of mechanical property data; the likely sources of difference between the test specimen and the bulk material properties of PU foam are addressed in §4.4.1.1. However, the important point is that the present results were obtained under exactly the same conditions as those for human OP and normal cancellous bone (Li and Aspden, 1997).

Previous studies have concentrated on either open- or closed-cell PU foams; here both are considered as possible models for OP bone. Open-cell and closed-cell PU foams have been reported to exhibit different responses to mechanical loads (Johnson and Keller, 2008). Open-cell foams are favoured for their compressive fatigue behaviour, where the localised single-cell crush band has been found to be more characteristic of cancellous bone, unlike the

expandable crush zone found in closed-cell foam under the same strain (Harte *et al.*, 1999; Keller, 1994). Closed-cell foam has been found to exhibit similar static mechanical properties to human cancellous bone, but different characteristics to human cadaveric bone in fatigue (Palissery *et al.*, 2004), thus supporting the use of 0.16 g.cm^{-3} PU foam as an OP bone model in fracture studies that do not involve fatigue. Although, in life, fatigue fracture is not relevant because of the natural processes involved in healing trabecular micro-fractures (Vernon-Roberts and Pirie, 1973).

For all the PU foams of different lengths and densities used in this study, the energy absorbed to yield was found to be negligible (Figure 4.7). Toughness is the energy absorbed to fracture (i.e. failure) and Smith *et al.* (1999) suggested a ‘modular’ elongation mechanism for the toughness of natural composites such as bone, whereby the domains within a single molecule unfold (or loops open) upon pushing or pulling, so that “sacrificial bonds” are broken before a strong bond is broken (if the force is large enough). Such behaviour cannot be exhibited in a homogeneous material like PU foam. Thus, PU foam may not be a suitable model when energy dissipation, for instance in cyclic loading tests, is of concern.

The results in this chapter suggest that it is difficult to find a synthetic material to mimic the properties of OP bone. In part this is due to the wide spread of results that have been published for real normal and OP bone (Li and Aspden, 1997). Figure 4.6 and Figure 4.7 show that the yield strength and the energy absorbed to yield are similar for the OP and normal bone. A possible explanation is that normal bone shows considerable individual

variability so that when bone tissue is lost, as a result of osteoporosis, from some individuals the resulting tissue has properties that resemble those of normal bone from other individuals.

Two different PU cylinder lengths were chosen to determine whether specimen dimensions would affect the results. Significant differences were found for E and the energy absorbed to yield (except for the 0.09 g.cm^{-3} PU foam) between the two PU foam cylinder lengths. This result is consistent with the findings of Keaveny *et al.* (1997) who found a weak dependence between E and specimen aspect ratio for cylindrical specimens of cancellous bone. Other studies on compression specimens of different geometries have also reported correspondingly different values for the modulus and strength of cancellous bone (Keaveny *et al.*, 1993b; Linde *et al.*, 1992). As in the present study, the dependence of E on specimen length is most likely to be caused by “trabeculae” side-artifacts and end-artifacts (Linde *et al.*, 1992) (see §4.4.1.1). The response of a cellular solid to compression is not simple. Video recordings, taken during the experiments, showed that deformation of the open-cell foams involved bending and buckling of the PU “struts”; failure involved fracture and consolidation. A similar structural response to compression has been observed in the trabeculae of cancellous bone (Gibson, 2005). This complicated response may be implicated in the dependence of the results on specimen geometry (§4.4.1.1). However, the most important conclusion is that any comparison of results from PU foam and bone should be for results obtained from specimens with comparable dimensions.

The mechanical properties of the PU foams used in this study have been derived from a single strain rate, in order to compare the results with those published for cancellous bone (Li and

Aspden, 1997). A useful future study would be to test the mechanical properties of the PU foams, considered in this study, when they are subjected to higher strain rates and then to compare the data with mechanical properties of cancellous bone tested at high strain rates. Any similarities found between the mechanical properties for PU foam and cancellous bone would further strengthen the case for using PU foams as a human cancellous bone model.

This study has shown that PU foams cannot capture all of the properties of bone; there are clear differences in the median values of E (Figure 4.5), yield strength (Figure 4.6) and energy absorbed to yield (Figure 4.7) between PU foams and cancellous bone. In part this is due to the microstructural differences between PU foam and cancellous bone (see §2.7). The 0.09 g.cm^{-3} open-cell PU foam may resemble the trabecular architecture of cancellous bone, but it is much weaker than real bone (Figure 4.5 and Figure 4.6). On the contrary, the microstructure of 0.16 g.cm^{-3} and 0.32 g.cm^{-3} closed-cell PU foams cannot be likened to that of cancellous bone (see §2.5.2 and §2.7), but the E and yield strength are comparable to cancellous bone (Figure 4.5 and Figure 4.6). Thus, the selection of PU foams as cancellous bone models involves a trade-off between its microstructure and its mechanical properties. With regard to modelling the degree of osteoporosis, this study has shown that PU foams are mechanically weaker with decreasing foam density, which suggests that various densities of PU foams could simulate different degrees of OP degeneration (Johnson and Keller, 2008).

Acknowledgement of the wide spread of results that have been published for real normal and OP bone (Li and Aspden, 1997) shows that the mechanical properties of some of the PU foams tested here do fall within the reported range (i.e. within the 5% and 95% confidence

limits); this forms the basis of this chapter's conclusions. As such, the E and yield strength of 0.09 g.cm^{-3} , 0.16 g.cm^{-3} and 0.32 g.cm^{-3} PU foams enable them to be used as mechanical bone models for very OP, OP and normal cancellous bone respectively. These PU foams were deemed to be a useful 'standard' test material for the mechanical evaluation of bone screws, which is why they have been selected for the experimental work described in Chapters 5-8.

4.7 Conclusions

- PU foam of density 0.16 g.cm^{-3} may prove suitable as an OP cancellous bone model when fracture stress, but not energy dissipation, is of concern.
- The 0.16 g.cm^{-3} PU foam is a good alternative for *in-vitro* testing because it has compressive Young's modulus and yield strength values similar to OP bone that has also been tested in compression.
- It has not been possible to characterise the foam through other forms of testing due to the lack of appropriate data on human bone to compare the results of this study with.
- The compressive mechanical properties of 0.09 g.cm^{-3} , 0.16 g.cm^{-3} and 0.32 g.cm^{-3} PU foams, determined from this study, enable them to be used as mechanical bone models for "worst case" OP, OP and normal human cancellous bone, respectively. In particular, these foams can be used for the mechanical testing of bone screws, which is described in the following chapters.

5. THE EFFECT OF SCREW INSERTION ANGLE AND THREAD TYPE ON THE PULLOUT FORCE OF BONE SCREWS IN NORMAL AND OSTEOPOROTIC CANCELLOUS BONE MODELS

5.1 Chapter Overview

This chapter compares the fixation of screws in normal and osteoporotic (OP) bone models. Section 5.2 introduces the study and §5.3 states the specific study aims. The materials and methods are presented in §5.4 and the results obtained are shown in §5.5. Section 5.6 begins with a general discussion of the results followed by some analytical sections, based on theory published by other researchers. The core findings from the screw pullout study are summarised in §5.7.

5.2 Introduction

Pullout force can be used to measure screw fixation strength (Thompson *et al.*, 1997). To date, work on screw pullouts has focused mainly on axial pullouts in cadaveric (Cordista *et al.*, 2006; Hilibrand *et al.*, 1996; Lotz *et al.*, 1997) and animal (Gausepohl *et al.*, 2001; Inceoglu *et al.*, 2006; Inceoglu *et al.*, 2004) bone and synthetic materials mimicking the properties of human bone (Gausepohl *et al.*, 2001; Hsu *et al.*, 2005; Inceoglu *et al.*, 2006).

Several studies report on the pullout of screws augmented with polymethylmethacrylate, calcium phosphate products and laminar hooks in OP bone (Becker *et al.*, 2008; Burval *et al.*, 2007; Cordista *et al.*, 2006; Hashemi *et al.*, 2009; Hilibrand *et al.*, 1996; Lotz *et al.*, 1997; Moore *et al.*, 1997; Yi *et al.*, 2008). This is because, without augmentation, axial screw pullout force from non-augmented/untreated OP bone has been reported to decrease with decreasing bone mineral density (Cook *et al.*, 2004; Dvorak *et al.*, 2005; Halvorson *et al.*, 1994; Okuyama *et al.*, 1993; Soshi *et al.*, 1991). For this reason, osteoporosis is sometimes considered a contra-indication for screw fixation, particularly in the spine (Coe *et al.*, 1990; Halvorson *et al.*, 1994; Okuyama *et al.*, 2001; Soshi *et al.*, 1991; Weinstein *et al.*, 1992). However, screw fixation to OP bone has been performed in the spine for cases of instability (after fracture), deformity, tumours, multi-segmental spinal stenosis (narrowing of the vertebral canal, which causes spinal cord and nerve compression) and neurological deficits that require decompression and stabilisation (Becker *et al.*, 2008; Heini, 2005; Hu, 1997; Wuisman *et al.*, 2000).

The work described in this study uses polyurethane (PU) foam to overcome the main problem in determining screw fixation strength in OP bone. The widespread variability in the mechanical properties of OP bone (Li and Aspden, 1997) make it difficult to distinguish effects caused by differences in screw fixation from those caused by bone specimen variability. In this study, the problem of variability was overcome by using PU foams of different densities that are suitable as models for representing the mechanical properties of normal and OP bone (Patel *et al.*, 2008; Chapter 4).

For OP bone, multiple sites of screw fixation are often used (Hu, 1997), which means that screws can be placed at various angles (Robert *et al.*, 2003). Only a small number of studies have investigated angled screws (Barber *et al.*, 1998; DiPaola *et al.*, 2008; Ilahi *et al.*, 2004; Jomha *et al.*, 1993; Kilincer *et al.*, 2007; Robert *et al.*, 2003; Skinner *et al.*, 1990; Sterba *et al.*, 2007; Zehnder *et al.*, 2009) and most are specific to a single anatomical site, such as the shoulder, knee and spine (Barber *et al.*, 1998; Ilahi *et al.*, 2004; Jomha *et al.*, 1993; Kilincer *et al.*, 2007; Skinner *et al.*, 1990; Sterba *et al.*, 2007). There has been a previous study of the pullout resistance of individual screws inserted at varying angles to the axis of pullout in PU foam (Robert *et al.*, 2003) but it was restricted to foams of a single density (0.32 g.cm^{-3}). In addition, a recent study has investigated the effects of screw orientation and load to failure of a plate-bone construct that was attached to 0.09 g.cm^{-3} PU foam (used to model severely OP bone); these authors noted that further study is required in bone of varying density to determine where the benefit of angled screws, to increase fixation strength, is lost (Zehnder *et al.*, 2009). No previous study has reported any general relationship between bone screw insertion angle and screw pullout force with reference to OP bone.

5.3 Purpose of the Investigation

The objective of this study was to determine how the pullout force of a bone screw is affected by the following factors: (i) screw insertion angle, (ii) screw thread type (cortical or cancellous) and (iii) the density of PU foam, representing different densities of bone. The findings are intended to determine the effect of screw insertion angles to achieve enhanced

screw fixation in OP bone. This is the first study to use a set of pre-defined screw insertion angles and investigate their effect in several models of bone with varying density.

5.4 Materials and Methods

5.4.1 PU Foam Samples

Three different PU foams were used: (1) closed-cell foam of density 0.32 g.cm^{-3} , (2) closed-cell foam of density 0.16 g.cm^{-3} (ASTM Grades 20 and 10, respectively (ASTM F1839-08, 2008)) and (3) open-cell PU foam of density 0.09 g.cm^{-3} . All foams were supplied as blocks ($130 \times 180 \times 40 \text{ mm}$) from Sawbones® Europe AB (Malmö, Sweden). A smaller block ($45 \times 60 \times 40 \text{ mm}$) was sawn from these blocks for each test. The Young's modulus and yield strength of these foams enable them to be used as models for: (1) normal, (2) OP and (3) very low density OP cancellous bone (Patel *et al.*, 2008; Chapter 4).

5.4.2 Bone Screws

Two types of bone screw were investigated (Figure 5.1): a cortical bone screw (4.5 mm diameter \times 30 mm length) and a cancellous bone screw (6.5 mm diameter \times 30 mm length). The cortical screw was not tapered. The cancellous screw had a 4° core taper angle; this was measured from a shadowgraph (Zeiss MP320 Measuring Projector, Carl Zeiss Ltd., Rugby, Warwickshire, UK). Both screws were manufactured from medical grade titanium alloy, Ti-

6Al-4V, in accordance with the British Standard, BS 3531-5.3:1991, and are available commercially (Surgicraft Ltd., Redditch, UK). Table 5.1 summarises the bone screw dimensions, which were determined from a series of measurements (thirteen and seven measurements for the cortical and cancellous screw respectively, in accordance with the number of screw threads) obtained using a stereo microscope (Leica MZ9.5), digital microscopy camera (UEye 3.1MP) and imaging software (Omnimet Imaging Software version 9.0r3) (all available in the Buehler Centre of Excellence, School of Mechanical Engineering, University of Birmingham, UK); supplied by Buehler, Coventry, West Midlands, UK. The screw lengths were measured six times using digital vernier callipers (Fisher Scientific UK Ltd., Loughborough, Leicestershire, UK).

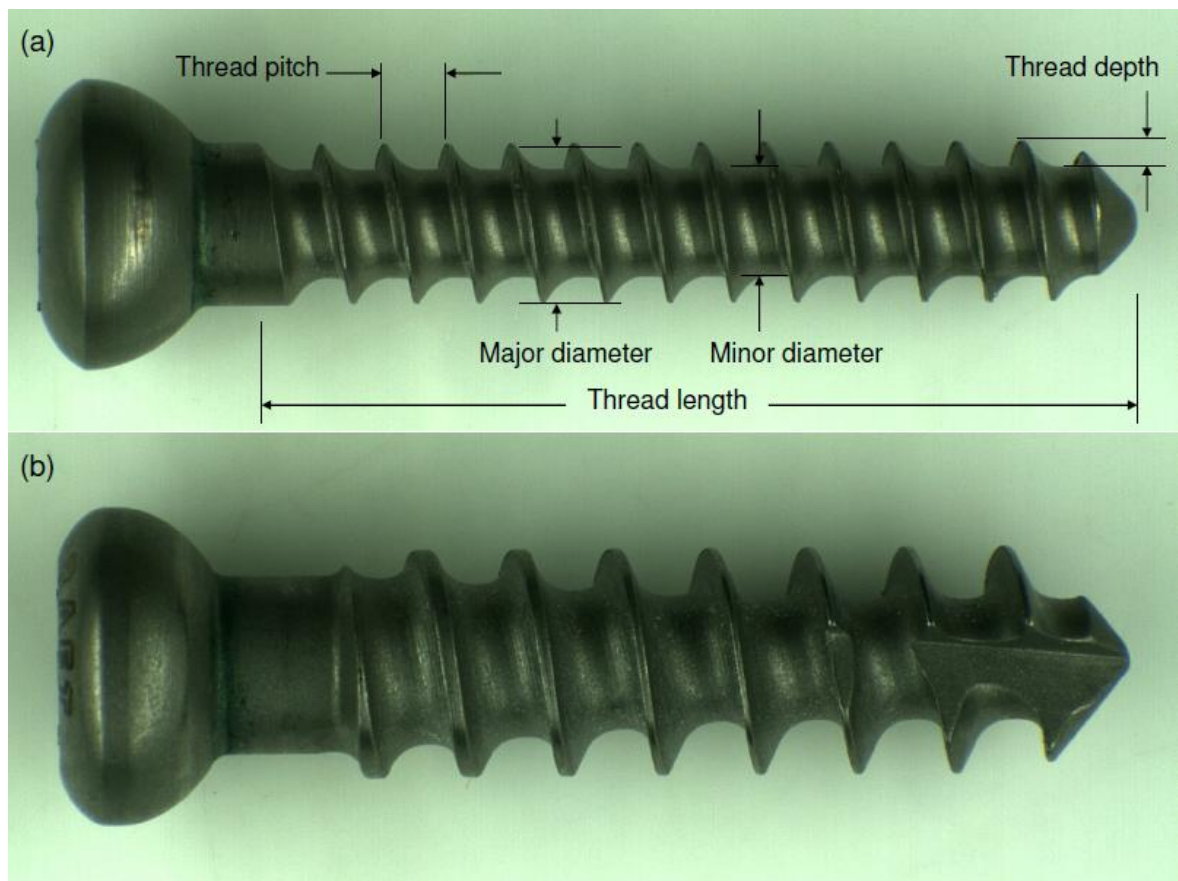


Figure 5.1 Screw thread terminology and screws used for the pullout tests: (a) 4.5 mm diameter cortical screw; (b) 6.5 mm diameter cancellous screw.

Table 5.1 Cortical and cancellous bone screw measurements expressed as mean \pm standard deviation; the dimensions were determined from a series of measurements (see §5.4.2) and thus represent the average value for the entire length of the screw shaft. All measurements are defined in Figure 5.1(a), except for the thread shape factor T , which is defined by equation 5.3 (see §5.6.2). The thread depth d was calculated using equation 5.4 (see §5.6.2). The standard deviations for d and T are estimated cumulative errors (Bevington, 1969). Dimensions are in mm, except for T , which is dimensionless.

Bone screw type	Major diameter, D_{maj}	Minor diameter, D_{min}	Thread length, L	Thread depth, d	Pitch, p	Thread shape factor, T
Ø 4.5 x 30 mm Cortical	4.67 ± 0.19	3.18 ± 0.09	23.93 ± 0.51	0.74 ± 0.11	1.83 ± 0.04	0.73 ± 0.11
Ø 6.5 x 30 mm Cancellous	6.73 ± 0.12	4.09 ± 0.53	22.65 ± 0.20	1.32 ± 0.27	2.60 ± 0.30	0.79 ± 0.19

5.4.3 Screw Pullout Testing

Pilot holes of 3.5 mm diameter, for the cancellous bone screw, and 3 mm diameter, for the cortical bone screw, were drilled into a PU foam test block before screw insertion. These pilot hole diameters were chosen by the author because they were just below the minor diameters of each screw (Table 5.1), thus allowing the screw thread to cut into the PU foam upon screw insertion; this approach is often used to ensure maximum strength of the screw thread purchase (Defino *et al.*, 2009). A swivel angle plate (Type 5150, J&L Industrial Supply, Wednesbury, West Midlands, UK) and digital protractor (Lucas AngleStar® DP45, Lucas Sensing Systems Inc., Hampton, Virginia, USA) were used to ensure accurate drilling of the pilot holes. Each screw was inserted into the foam block through a pullout fixture that was tailor-made to the desired screw angle (Figure 5.2 and Figure 5.3) and was hand-

tightened by a single investigator using a hexagonal key, until the head of the screw met the surface of the pullout fixture; this procedure ensured that all screws were inserted under the same conditions. The cortical and cancellous screws were inserted to controlled depths in the same materials. Thus, although the insertion torques were not explicitly controlled, the technique used is completely reproducible. The experimental design was intended to mimic surgical procedure in which screws are inserted to a required depth. However, in these experiments, the torques were implicitly controlled because screws were inserted into materials with controlled compositions.

Various checks were in place to ensure that each screw was inserted into the PU foam at the correct angle. Firstly, a swivel angle plate and digital protractor, as described above, were used to ensure that the pilot hole was drilled at the correct angle in the PU foam. Secondly, a template was drawn around each pullout fixture that was tailor-made to the desired screw angle; the angle from each template outline was then measured, using a protractor, to verify that the fixture had been manufactured to the appropriate screw angle. Thus, upon screw insertion, the screw was lined up parallel to the wall of the angled pullout rig (Figure 5.2 and Figure 5.3) so that it could follow the path made by the pilot hole in the PU foam. Radiographs could have been used to confirm the screw angle post-insertion (Erkan *et al.*, 2010); this equipment was not available at the time of testing. However, given the checks made in the present study, the errors associated with the screw insertion angle were considered to be negligible when compared with other random errors of measurement (see error bars in Figure 5.8 and Figure 5.9).

Following screw insertion, the pullout fixture, engaged with the bone screw head, was attached to the actuator of an ELF3300 materials testing machine (Bose Corporation, ElectroForce Systems Group, Minnetonka, MN, U.S.A.). The bottom part of the test set-up, involving the PU foam block, was placed in a custom-made rig attached to a plate on the machine's load cell (Figure 5.2 and Figure 5.3).

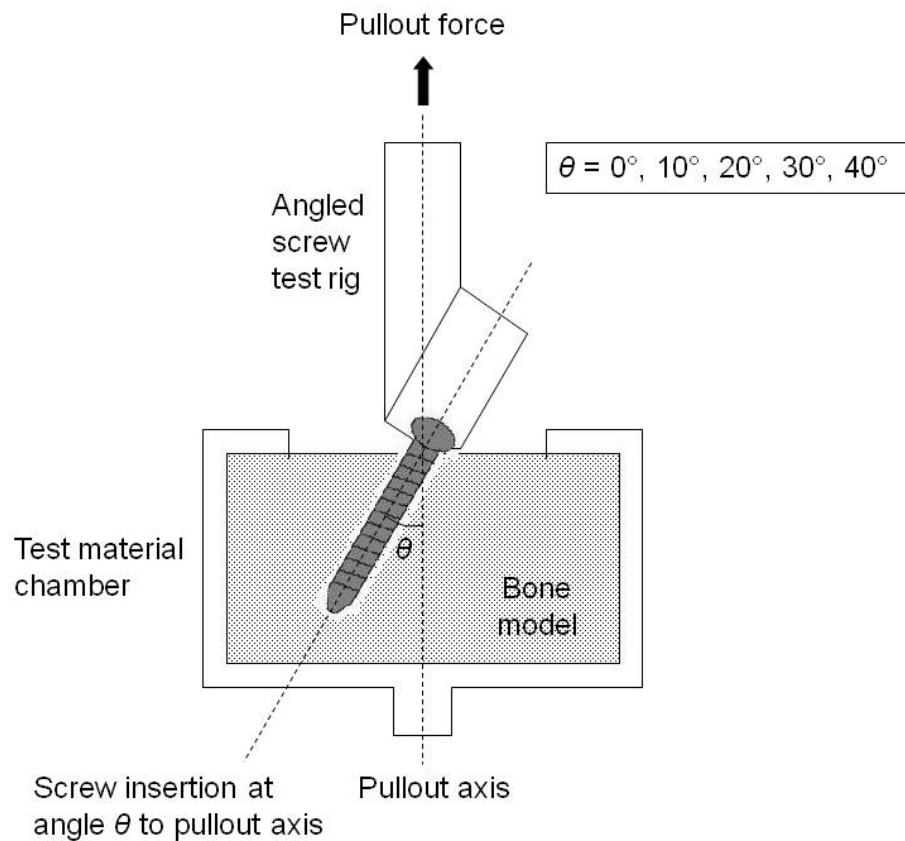


Figure 5.2 Pullout test set-up for screws inserted at angles in PU foam. The cortical and cancellous bone screws were inserted via custom-made angled screw test rigs and into normal and OP bone models.

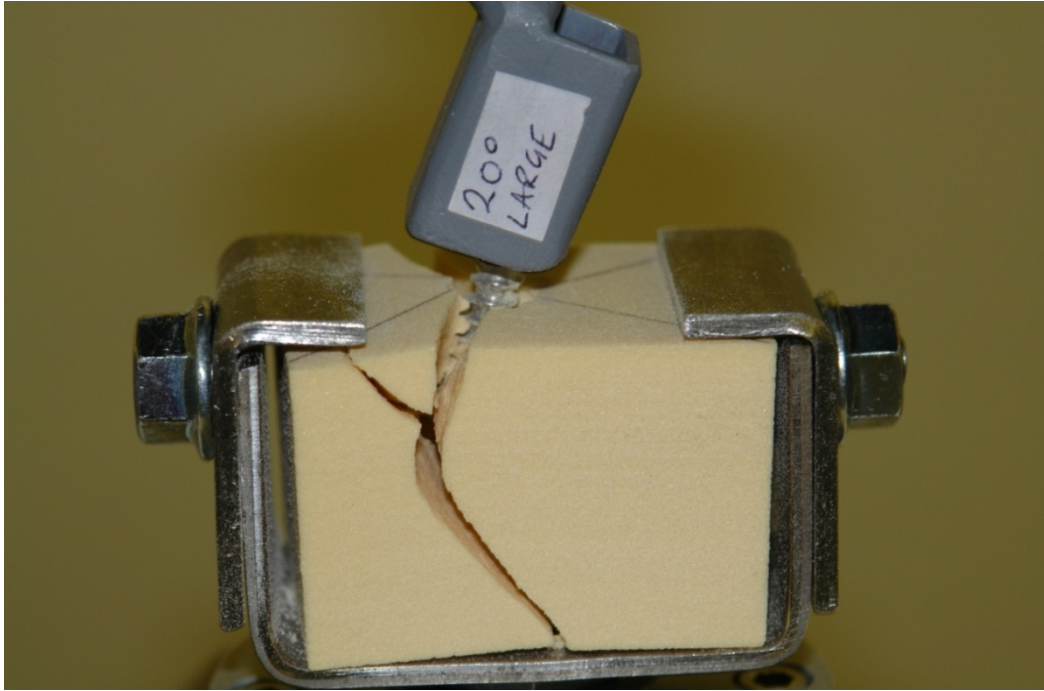


Figure 5.3 Pullout of the cancellous bone screw, placed at 20° to the vertical (pullout axis), from 0.16 g.cm⁻³ PU foam used as a model for OP cancellous bone (Patel *et al.*, 2008; Chapter 4).

Each screw was pulled by its head and along the axis perpendicular to the top surface of the test block (Figure 5.2), at a rate of 0.1 mm.s⁻¹ (Battula *et al.*, 2006), under displacement control. Load and displacement values were recorded and the maximum load generated during screw pullout was defined as the pullout force of the screw (Thompson *et al.*, 1997). Six pullout tests were performed for each condition of screw insertion angle (0°, 10°, 20°, 30°, 40° to the axis of pullout), screw type (cortical screw thread, cancellous screw thread) and PU foam density (0.09 g.cm⁻³, 0.16 g.cm⁻³, 0.32 g.cm⁻³). The same cortical and cancellous screw was used for all tests because of the comparatively low stiffness and strength of the PU foam when compared to the titanium alloy bone screws. The Young's modulus of the PU foam is reported to range between 0.3-145 MPa (Patel *et al.*, 2008), based on mean values, whilst the Young's modulus of titanium alloys is reported to range between 100-120 GPa (Gere and

Timoshenko, 1997). The tensile strength for the 0.16 g.cm^{-3} and 0.32 g.cm^{-3} PU foam is reported as 2.1 MPa and 5.6 MPa respectively (Sawbones® Europe AB, Malmö, Sweden), whilst the ultimate tensile strength for titanium alloys is reported as 1 GPa (Hibbeler, 2004). There was no observable damage to the screws following a test; the screws were readily inserted for further tests, indicating that the threads were not yet blunt or deformed. Appendix E provides examples of the variable pattern of results generated from using the same screw.

5.4.4 Statistical Analysis

Peirce's criterion (see Appendix F) was used to test for and exclude statistical outliers (Hawkins, 1980; Peirce, 1852; Ross, 2003). Statistical calculations were performed using MINITAB® Release 15 Statistical Software (Minitab Inc., Pennsylvania, USA). Normality of the distributions was assessed using the Anderson-Darling test (Bland, 2000). Data were compared using analysis of variance (ANOVA) and Tukey's Honestly Significant Difference multiple comparison tests (Bland, 2000). The ANOVA indicated whether there was a significant difference between test groups. The Tukey test identified between which groups there was a significant difference. Linear regression analysis was used to determine how pullout force changes with the screw angle using a simplistic linear model; if there is a trend between the screw pullout force and insertion angle, then this can be approximated to a straight line and hence a linear relationship (Bland, 2000). The significance level was set at 0.05 for all tests.

5.5 Results

5.5.1 Screw Pullout Failure Mode

The mode of pullout failure depended on the angle between the screw and pullout axes. For the screws placed axially (0° insertion angle) and sometimes at 10° , the observed mechanism of failure was stripping of the internal screw threads generated within the PU foam by screw insertion. However, Figure 5.3 shows the mode of pullout failure for screws inserted at angles to the pullout axis (most screws inserted at 10° and at greater angles); failure involved fracture of the PU block to produce one or more fragments.

5.5.2 Screw Force-Displacement Curves

A typical force-displacement curve from the screw pullout tests is given in Figure 5.4; there were up to four identifiable phases during screw pullout. Phase 1 of the curve showed the sudden rise in the pullout force required to initially dislodge the screw and cause the primary structural collapse of the cancellous material (PU foam) at the screw-bone interface, i.e. ‘failure’ at the point when the screw pullout force was at a maximum. Phase 2 showed a decrease in the force after failure; when the screw moved relatively easily through the ‘bone’ material around the internal screw threads that had collapsed. Phase 3 demonstrated an attempt to level off the force to approximately half of the maximum pullout force; a resistive

force that likely came from the friction opposing the direction of screw motion, in addition to resistance from the undamaged areas of bone material that would be along the screw motion path. Phase 4 was characterised by a gradual decrease in the force, with the odd area of screw resistance (marked by a rise in force), as the screw emerged fully from the PU block.

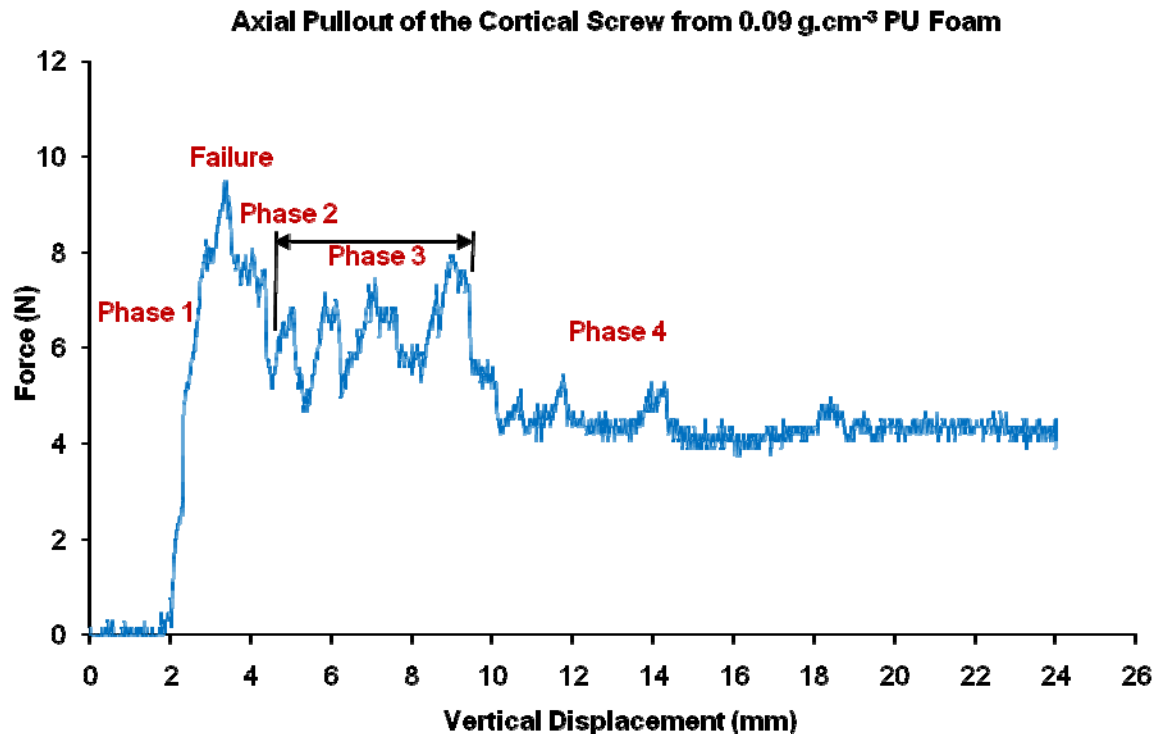


Figure 5.4 A typical force-displacement curve from the screw pullout tests; four distinct phases were identified. Note that the end forces in Phase 4 account for the weight of the pullout rig, after full extraction of the screw.

For screw pullout from 0.09 g.cm^{-3} PU foam, most of the force-displacement curves were similar to Figure 5.4; exceptions were the force-displacement curves that had two or more maximum (or close to maximum) peaks (instead of the usual one) and then a levelling off of the pullout force (Figure 5.5). Such discrepancies are expected with using an open-cell foam material that is highly prone to having material inconsistencies.

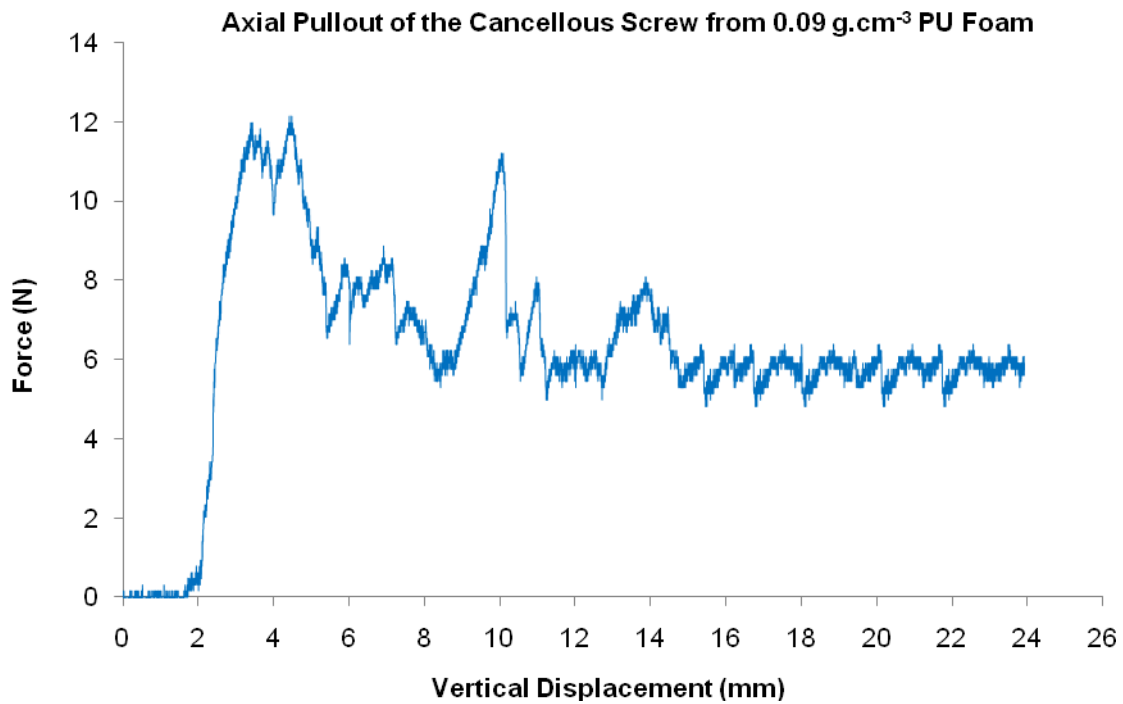


Figure 5.5 Example of a force-displacement curve with multiple maximum (or close to maximum) peaks, obtained from a screw pullout test using 0.09 g.cm⁻³ open-cell PU foam. Note that the end forces account for the weight of the pullout rig, after full extraction of the screw.

For screw pullout from the 0.16 g.cm⁻³ and 0.32 g.cm⁻³ PU foams, the force-displacement curves were smoother, had a more pronounced maximum peak and often lacked a Phase 3 (especially for the 0.32 g.cm⁻³ foam, see Figure 5.6) when compared to Figure 5.4; these were closed cell foams that provided greater resistance up to the maximum screw pullout force, but were unable to provide a constant resistive force after the maximum pullout force was attained, unlike the 0.09 g.cm⁻³ open cell foam that probably experienced a repetitive cycle of ‘trabeculae’ fracture and consolidation during screw pullout.

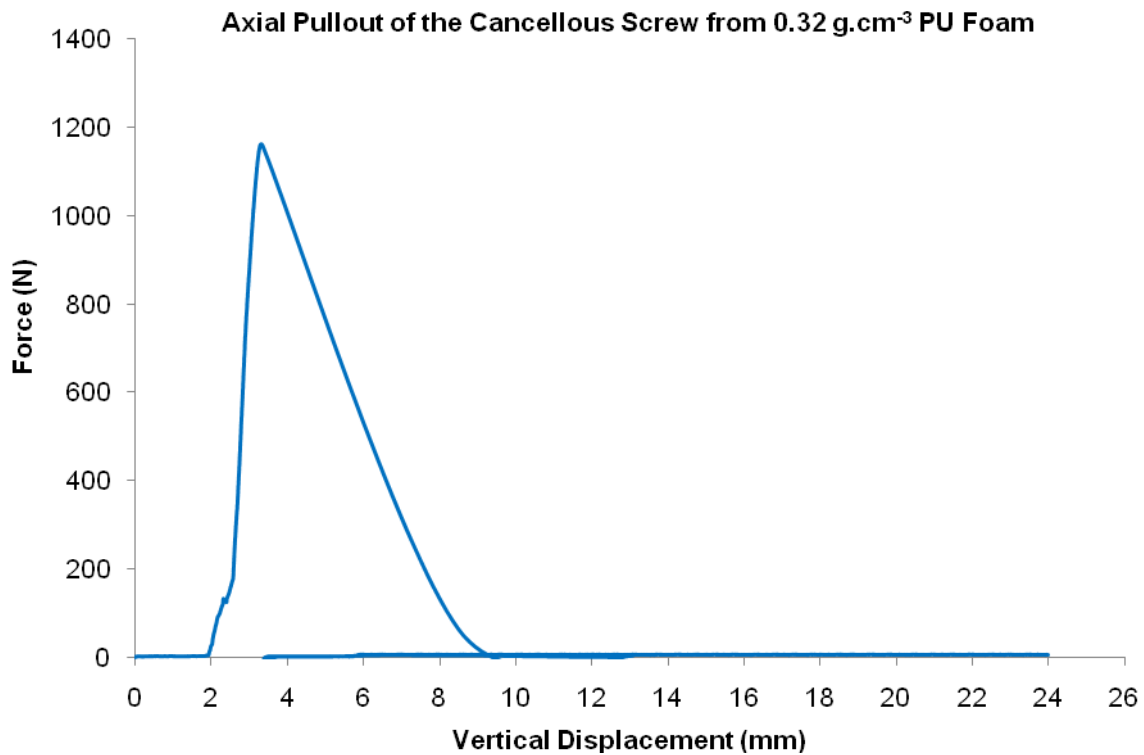


Figure 5.6 Example of a smooth force-displacement curve, without a ‘Phase 3’, obtained from a screw pullout test using 0.32 g.cm^{-3} closed-cell PU foam. Note that the blue line at Force = 0 N, from a displacement of about 3 mm to 9 mm, accounts for the sudden movement of the screw (and the associated test rig) immediately after failure, when a slight rebound of the screw was observed.

For the various screw insertion angles used, the force-displacement curves did not differ greatly for pullout from the 0.09 g.cm^{-3} and 0.16 g.cm^{-3} PU foams. However, screw pullout from 0.32 g.cm^{-3} PU foam demonstrated a bumpier peak region (after failure) as the screw insertion angle was increased (Figure 5.7); this is probably a result of fluctuating resistance provided by the broken material above the angled screw after failure (the mass of broken material above the screw would increase with an increase in the screw insertion angle used). In general, the cortical screw tended to exhibit more of a Phase 3 than the cancellous screw, implying that the cortical screw was able to provide more resistance, post screw failure, compared to the cancellous screw; the cortical screw has a smaller pitch and therefore might

have encountered obstruction, from any undamaged internal threads, earlier and more frequently than the cancellous screw along the screw motion path.

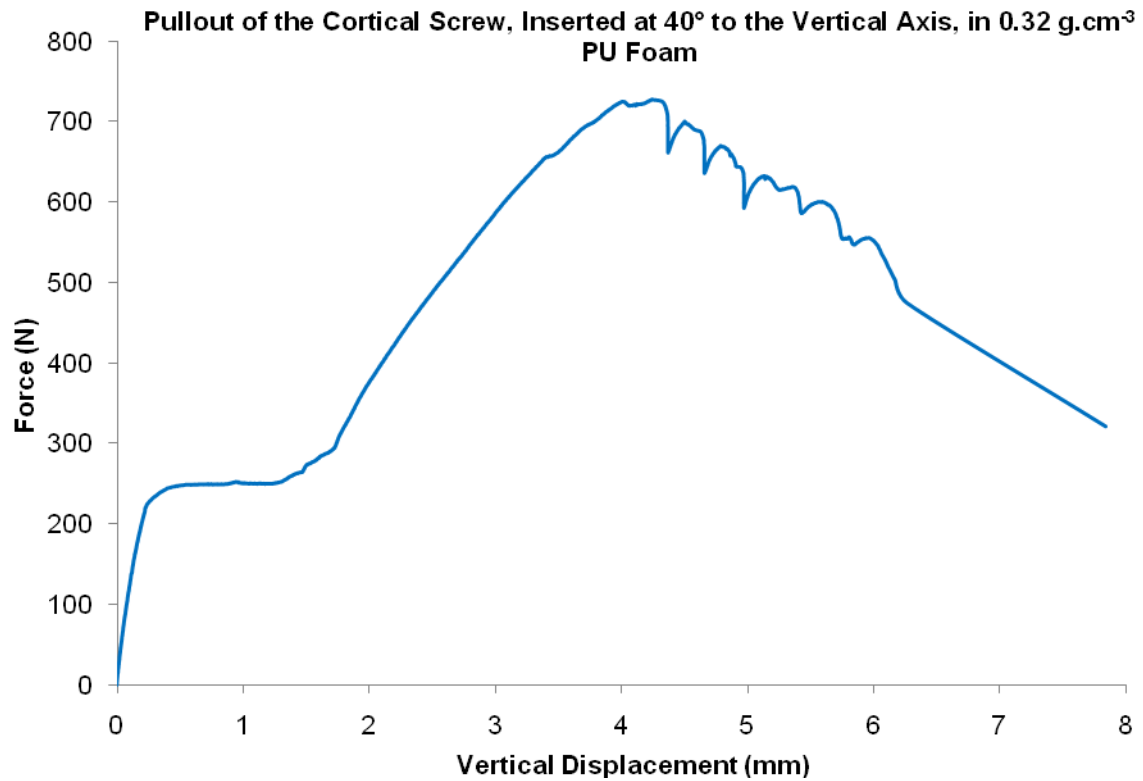


Figure 5.7 A close-up section of the force-displacement curve for pullout of an angled screw from 0.32 g.cm⁻³ PU foam; screw pullout from 0.32 g.cm⁻³ PU foam demonstrated a bumpier peak region (after failure) as the screw insertion angle increased, especially for the cortical screw.

5.5.3 Screw Pullout Force

Figure 5.8 and Figure 5.9 show mean values of screw pullout force for the cortical and cancellous bone screws respectively. All data sets were found to be normally distributed.

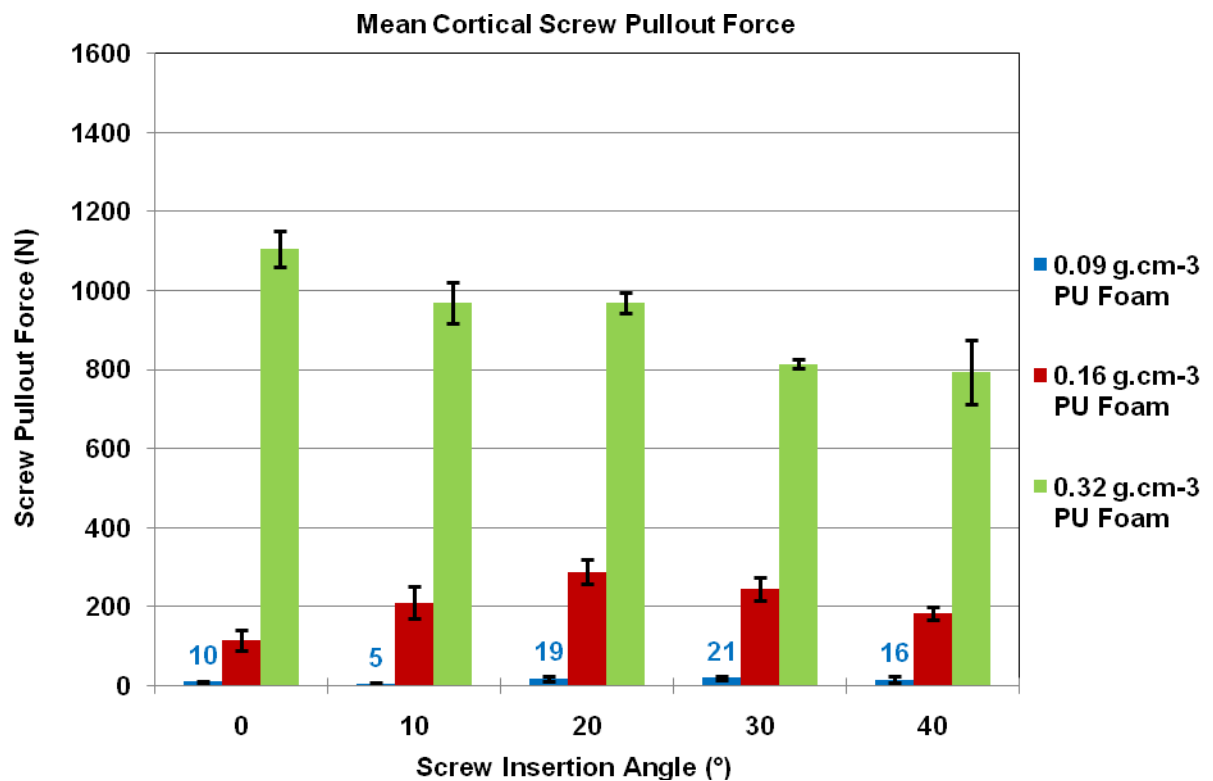


Figure 5.8 Bar chart to show the mean cortical screw pullout forces; the error bars represent the standard deviation for each data set. The mean represents up to six data points, depending on the number of excluded statistical outliers (there was roughly one outlier in every three data sets). Mean cortical screw pullout forces from 0.09 g.cm⁻³ open-cell PU foam are explicitly shown because of the relatively small values that were found.

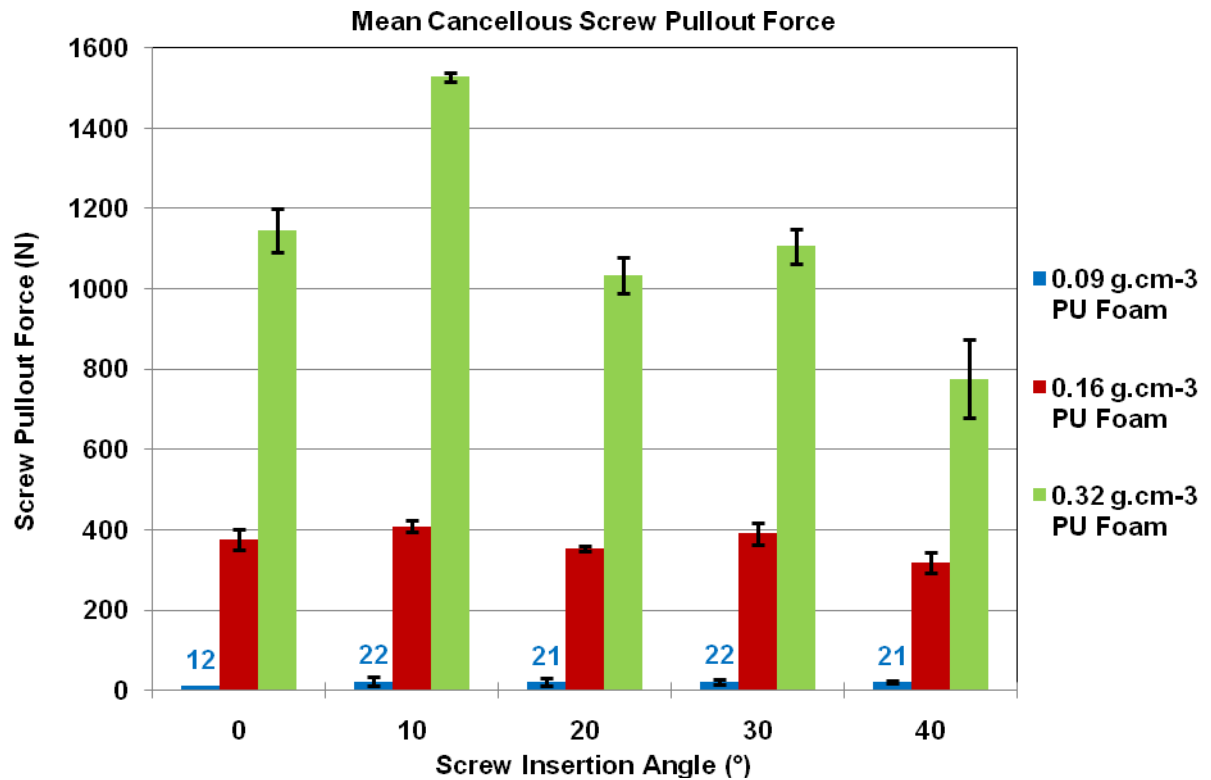


Figure 5.9 Bar chart to show the mean cancellous screw pullout forces; the error bars represent the standard deviation for each data set. The mean represents up to six data points, depending on the number of excluded statistical outliers (there was roughly one outlier in every two data sets). Mean cancellous screw pullout forces from 0.09 g.cm⁻³ open-cell PU foam are explicitly shown because of the relatively small values that were found.

ANOVA and Tukey's Honestly Significant Difference multiple comparison tests showed that the cancellous screw had a significantly higher pullout force than the cortical screw ($p < 0.05$). For both screws, there was a significant ($p < 0.05$) increase in pullout force with increasing PU foam density. Table 5.2 shows the significant and non-significant statistical relationships detected for screw pullouts between the different screw insertion angles.

Table 5.2 Relationships detected for screw pullouts between the different screw insertion angles using ANOVA and Tukey's Honestly Significant Difference multiple comparison tests. The significance level was set at 0.05 for all tests.

Significant difference ($p < 0.05$)	No significant difference
$0^\circ > 30^\circ, 40^\circ$	$0^\circ \& 20^\circ$
$10^\circ > 0^\circ, 20^\circ, 30^\circ, 40^\circ$	$20^\circ \& 30^\circ$
$20^\circ > 40^\circ$	
$30^\circ > 40^\circ$	

Regression analysis showed only one significant relationship; there was a high linear correlation ($R^2 = 0.922$, $p = 0.009$) between the mean cortical screw pullout force and screw angle in the 0.32 g.cm^{-3} PU foam. No other significant relationships existed between the mean screw pullout force and angle for all remaining test conditions.

5.6 Discussion

5.6.1 General Discussion

This study has investigated several factors affecting screw pullout, by systematically varying the screw type, host material density and screw insertion angle. It is a unique study because, for the first time, the pullout force of individual angled screws has been measured in models of bone corresponding to varying degrees of osteoporosis. From a literature review, the author found that the benefits often gained by an increase in the stability of screws inserted at

angles, in healthy bone (Kuzhupilly *et al.*, 2002), required quantification and better understanding with regard to OP bone.

In this study, a possible explanation for the greater cancellous screw pullout force, compared to cortical screw pullout, is that the PU foam test material has been designed to mimic human cancellous bone, making the cancellous screw thread more favourable for this host material. The difference in results between the pullout force of the cortical and cancellous screw highlight how thread design can influence screw fixation. Several studies have addressed this point, particularly Gausepohl *et al.* (2001), who compared the pullout of cortical, cancellous and fine machine screws, concluding that the cancellous bone screws were superior to all other screws in both PU foam and bovine cancellous bone test materials. Asnis *et al.* (1996) isolated different parameters of cancellous screw threads for their effect on holding strength and found that the order of importance was (i) host material density, (ii) major diameter of the screw, (iii) thread pitch and (iv) minor diameter of the screw (see Figure 5.1). These findings support an earlier and similar study by DeCoster *et al.* (1990). Furthermore, Krenn *et al.* (2008) recently tested three different pedicle screws of the same length and diameter, where the pullout forces were found to depend on thread design.

This study used three different densities of PU foam to model OP (0.09 g.cm^{-3} and 0.16 g.cm^{-3} foam) and normal (0.32 g.cm^{-3} foam) human cancellous bone. These foams are a valid model for OP and normal cancellous bone (Patel *et al.*, 2008; Chapter 4) and the higher density foam has been used in several studies to investigate orthopaedic devices (Chapman *et al.*, 1996; Iesaka *et al.*, 2005). For both screws used in this study, the screw pullout force decreased

with decreasing PU foam density (modelled as increasingly OP bone material). Lower screw pullout force was also reported in an OP bone model compared to a normal bone model for self-tapping bone screws (Battula *et al.*, 2006; Schoenfeld *et al.*, 2008). For OP and normal human cancellous bone, the literature reports axial screw pullout ranges of 58 – 496 N and 560 – 1540 N, respectively (Cook *et al.*, 2000; Cordista *et al.*, 2006; Halvorson *et al.*, 1994; Hilibrand *et al.*, 1996; Lotz *et al.*, 1997; Schoenfeld *et al.*, 2008; Soshi *et al.*, 1991). The relative nature of these reported screw pullout forces is comparable to that found in the present study, where the axial screw pullout force (combining results for both screws) ranged from 78 – 405 N in 0.16 g.cm⁻³ PU foam (OP bone model) and from 1059 – 1195 N in 0.32 g.cm⁻³ PU foam (normal bone model), thus validating these PU foams as suitable bone analogue materials for the study of screw pullout force trends.

Screws placed axially or up to 10° tend to have greater fixation strength; exceptions were for all screws placed in 0.09 g.cm⁻³ PU foam and for the cortical screw in 0.16 g.cm⁻³ PU foam. Pullout of screws placed at 20°, 30° and 40° show mixed results. The regression analysis between pullout force and screw angle shows only one clear trend; screw pullout force decreased when the screw angle increased for the cortical screw in 0.32 g.cm⁻³ PU foam (Figure 5.8). The results for each density of PU foam are discussed in the following paragraphs.

For the 0.09 g.cm⁻³ PU foam, used to model very low density OP cancellous bone, pullout force almost doubled when the cancellous screw was placed at 10°, 20°, 30° and 40° instead of 0°. Figure 5.9 shows that values for the mean cancellous screw pullout force at 10°, 20°, 30° and 40° were significantly higher than at 0°.

30° and 40° screw angles hardly differed from each other. Similarly, the cortical screw demonstrated low pullout forces at 0° and 10°, and the pullout force was found to double for cortical screw placement at 20°, 30° and 40° in 0.09 g.cm⁻³ PU foam (Figure 5.8).

For the 0.16 g.cm⁻³ PU foam, used to model OP cancellous bone, pullout results for the cancellous screw clearly show that a 10° placement improves fixation strength compared to all other angles (Figure 5.9). For the cortical screw, Figure 5.8 shows a general benefit in placing this screw at angles, particularly at 20° and 30°, to increase its pullout force.

For the 0.32 g.cm⁻³ PU foam, used to model normal cancellous bone, the lowest pullout force was recorded for cancellous and cortical screws placed at 40°. This suggests that there is little benefit in placing screws at 40° in normal bone. Placement of the cancellous screw at 10° in the normal bone model recorded the highest pullout force, when compared to screw placement at all other angles tested in this study. This was not the case for the cortical screw, which showed greatest resistance to screw pullout when placed at 0°. Robert *et al.* (2003) also investigated pullout of 4.5 mm diameter cortical screws placed at 0°, 10°, 20°, 30° and 40° to the axis of pullout in 0.32 g.cm⁻³ PU foam; their findings are in agreement with the results from this current study for cortical screw pullout from 0.32 g.cm⁻³ PU foam.

Failure of the axially (0°) placed screws was, generally, observed by the stripping of the internal screw threads generated within the PU foam by screw insertion; this was sometimes the case for failure of screws inserted at 10° as well. In contrast, the mechanism of screw

failure for screws inserted at 10°, 20°, 30° and 40° to the pullout axis was observed to have two phases. Firstly, the screw pullout force was resisted by compression of the foam material above the angled screw. In a second phase, the region of compressed foam would break away from the foam block, such that the surrounding area of the screw normally consisted of fragmented test material (Figure 5.3). The second phase would occur once the screw has applied a 'critical load' on the compressed foam region. This suggests that the compressed foam provides increasing resistance, up to an undefined point, as the screw pullout force increases. Clinically, this suggests that compressed OP bone is stronger than unloaded OP bone. Interestingly, the cancellous and cortical screw pullout force from the 0.09 g.cm⁻³ foam, used to model very low density OP bone, increased when inserted at 20°, 30° and 40° as opposed to 0° and 10° (Figure 5.8 and Figure 5.9); a sufficiently angled screw may have provided better compressive resistance by this foam to screw pullout. This description of the screw failure mechanism also explains how the screw pullout force increased with increasing PU foam density; a larger material mass will offer greater resistance to an applied force.

Inevitably, this study has some limitations. Firstly, pullout forces are unable to replicate the physiological, and often multi-directional, loading patterns that bone screws are subjected to *in-vivo* (see Chapter 7); however, pullout force is a useful measure of screw fixation strength and enables comparison with other studies. Secondly, the cancellous and cortical screw had different diameters (Table 5.1), thus it is difficult to conclude that it is the design of the cancellous screw (with the larger diameter) that is responsible for its superior fixation strength. Thirdly, a similar point can be made with regard to the pilot holes used for the cancellous (3.5 mm diameter pilot hole) and cortical (3 mm diameter pilot hole) screw; the different pilot hole sizes may have affected the screw pullout force. However these screws,

which were standard cancellous and cortical screws obtained from the same manufacturer, are not designed to have the same screw diameters (An, 2002). Aside from their geometric differences, the cancellous and cortical screws were chosen to investigate how the relationship between screw insertion angle and screw pullout force is affected by screw thread types that are used for different bone structures.

The results of this study indicate that the effect of screw insertion angle on pullout force cannot be considered in isolation from the other parameters. In a model of very low density OP bone (0.09 g.cm^{-3} PU foam), screws inserted at 20° , 30° and 40° demonstrated greater pullout forces compared to screws inserted at 0° and 10° (Figure 5.8 and Figure 5.9). For the OP cancellous bone model (0.16 g.cm^{-3} PU foam), it is difficult to identify a clear trend between screw angle and fixation, because the cortical and cancellous screw recorded peak mean pullout forces at different insertion angles (20° and 10° respectively); this clearly shows the importance of screw parameters and their influence on screw fixation in OP bone. In the normal cancellous bone model (0.32 g.cm^{-3} PU foam), screws inserted at 0° and 10° exhibited larger pullout forces compared to screws inserted at 20° , 30° and 40° (Figure 5.8 and Figure 5.9); the lowest pullout forces recorded were for screws inserted at 40° , which suggests there is no benefit in placing screws at 40° in normal bone. Screw insertion angles of 0° , 10° , 20° , 30° and 40° were chosen because these angles have been used for screw fixation at various anatomical sites and within plate-bone constructs (Barber *et al.*, 1998; Ilahi *et al.*, 2004; Jomha *et al.*, 1993; Kilincer *et al.*, 2007; Robert *et al.*, 2003; Skinner *et al.*, 1990; Zehnder *et al.*, 2009).

5.6.2 Predicted Shear Failure Force for Axial (0°) Screw Pullout

Given that failure of the axially (0°) placed screws was, generally, observed by the stripping of the internal screw threads generated within the PU foam by screw insertion, the predicted shear failure force can be calculated. When a screw pulls out of a material in shear, by stripping the internal thread of the host material, the pullout force is given (Asnis *et al.*, 1996; Chapman *et al.*, 1996) by:

$$F_s = SA_s \quad (5.1)$$

where S is the shear strength of the host material and A_s is the thread shear area. For the cortical screw used in this study, i.e. a cylindrical screw (Figure 5.1a), equation 5.1 can be expressed (Asnis *et al.*, 1996; Chapman *et al.*, 1996; Oberg *et al.*, 1988) as:

$$F_s = S(L\pi D_{maj})T \quad (5.2)$$

where L is the length of screw thread that engages with the host material, D_{maj} is the major diameter of the screw (Figure 5.1a) and T is the thread shape factor of the screw. T is defined (Asnis *et al.*, 1996; Chapman *et al.*, 1996) by:

$$T = (0.5 + 0.57735d/p) \quad (5.3)$$

where p is the pitch of the screw (Figure 5.1a) and d is its thread depth defined (Asnis *et al.*, 1996; Chapman *et al.*, 1996) by:

$$d = (D_{maj} - D_{min})/2 \quad (5.4)$$

where D_{min} is the minor (core) diameter of the screw (Figure 5.1a). Values of T , for the cortical and cancellous screw used in this study, are shown in Table 5.1.

For the cortical screw, equations 5.2, 5.3 and 5.4 can be combined to give the following equation for pullout force:

$$F_s = SL\pi D_{maj} \left[0.5 + \frac{0.288675(D_{maj} - D_{min})}{p} \right] \quad (5.5)$$

Equation 5.5 shows that axial screw pullout force increases with increasing major diameter, increasing thread length and increasing thread depth but decreases with increasing thread pitch.

The cancellous screw used in this study is a conical screw (Figure 5.1b). As the core screw diameter decreases, the flank overlap area (FOA) increases; the FOA is the projected area of the ‘bone’ that is covered by the threads of the screw (Krenn *et al.*, 2008). The FOA per individual thread can be calculated by determining the difference between the projected areas of the outer screw diameter (D_{maj}) and the core diameter (D_{min}). To account for different numbers of threads along the inserted screw length, the number of threads has to be calculated from the ratio of L and p . Therefore equation 5.1 can be expressed, by using the equation for the total FOA of a conical screw (Krenn *et al.*, 2008), as:

$$F_s = S \left[\frac{\pi}{4} (D_{maj}^2 - D_{min}^2) \right] \left(\frac{L}{p} \right) \quad (5.6)$$

where S , D_{maj} , D_{min} , L and p are as defined above.

Values of S , required to calculate F_s from screw dimensions, were obtained from the suppliers of the PU foams (Sawbones® Europe AB, Malmö, Sweden). Unfortunately, the errors in the values of S were not available from the suppliers and, thus, the errors in the predicted shear failure forces cannot be determined; although any such error would be negligible due to the large spread of experimental results (Table 5.3).

A one-sample t -test of the mean was used to generate 95% confidence intervals and test whether the experimental mean axial (0° insertion angle) screw pullout force originated from a population with a mean equivalent to the predicted shear failure force. The significance level was set at 0.05 for all tests.

Since failure occurred by stripping of the internal thread in the PU foam, it should be valid to use equations 5.5 and 5.6 to predict the axial pullout force for the cortical and cancellous screw respectively. The predicted shear failure forces for axial screw pullout from 0.16 g.cm^{-3} and 0.32 g.cm^{-3} PU foam, calculated using equations 5.5 and 5.6, are shown in Table 5.3. Predictive values for screw pullout from 0.09 g.cm^{-3} PU foam could not be calculated because the ultimate shear stress of this foam was unknown and is difficult to measure, because it is an open-cell foam (see §5.6.4 for estimates of the shear strength). The only theoretical predictions that fell within the 95% confidence intervals for the experimental measurements were for the cortical screw in the 0.32 g.cm^{-3} PU foam.

Table 5.3 Comparison of the mean (\pm standard deviation) axial screw pullout results with calculated theoretical values using equations 5.5 and 5.6, for the cortical and cancellous screw respectively. For axial pullout $\theta = 0^\circ$ (see Figure 5.2).

PU foam density (g.cm^{-3})	Predicted shear failure force (kN)		Experimental mean axial screw pullout force (kN)	
	Cortical screw	Cancellous screw	Cortical screw	Cancellous screw
0.16	0.41	0.31	0.12 ± 0.03	0.38 ± 0.03
0.32	1.11	0.84	1.11 ± 0.05	1.15 ± 0.06

Table 5.3 shows that equations 5.5 and 5.6 provide a reasonable estimate for the pullout force of a bone screw that is pulled out along its axis. However, the only statistically significant agreement between theoretical prediction and experimental observation was obtained for the cortical screw in 0.32 g.cm^{-3} density PU foam.

Equations 5.5 and 5.6 do have limitations; the relationships may be more applicable to engineering screws rather than bone screws. In particular, T does not account for other thread shapes, such as those illustrated in Figure 5.10; it only accounts for the thread depth and pitch (equation 5.3). With considerable additional study, equations 5.5 and 5.6 could be improved by using a more detailed thread shape factor, incorporating other screw geometry such as thread end radii or the thread angle. Wang *et al.* (2009) recently reported that the proximal angle of the screw thread is a critical design variable affecting the pullout strength of cancellous bone screws. Another limitation with equations 5.5 and 5.6 is that they do not consider the microstructure of cancellous bone (see §2.5.2) or PU foam. It is difficult to incorporate parameters such as the bone volume fraction (BV/TV), trabecular thickness

(Tb.Th), trabecular spacing (Tb.Sp) and trabecular number (Tb.N), into any numeric equation because of the complex trabecular structure and associated variable porosity within cancellous bone; if these parameters were to be included in numeric equations, then the calculations would only be representative of a small region of cancellous bone.

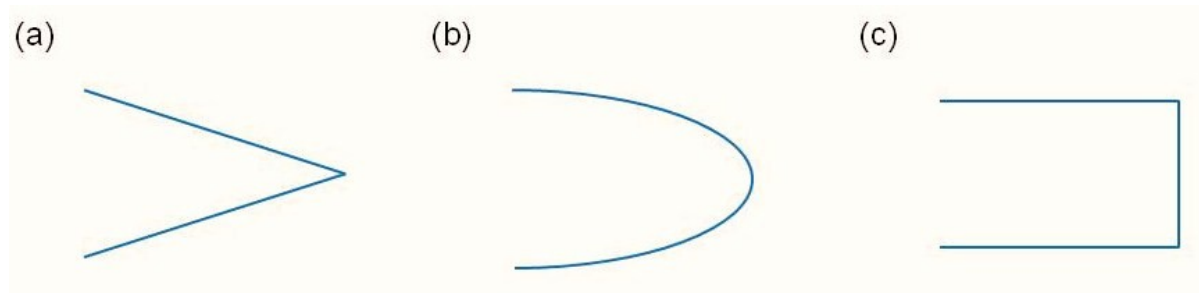


Figure 5.10 Examples of thread shapes not accounted for by the thread shape factor, T , (equation 5.3); (a) saw tooth, (b) rounded and (c) square thread shapes.

Theoretically, axial screw pullout force increases with increasing thread depth and decreasing pitch (equation 5.3). Practically, there is a limit at which the axial pullout force “levels off”, when the internal threads of the weaker host material become too thin to resist pullout, such that pullout force starts to decrease. This limit would vary with host material density; in OP bone, the effects of thread depth and pitch would appear to have greater importance than in normal bone in achieving adequate screw fixation. Incidentally, the cancellous screw used in this study had a slightly larger thread shape factor than the cortical screw (Table 5.1), which helps to explain the greater cancellous screw pullout force compared to cortical screw pullout (Figure 5.8 and Figure 5.9). Further study is required to determine an optimum value for T .

5.6.3 Relationship between Bone Shear Strength and Screw Pullout Force

Equation 5.1 demonstrates an important relationship between bone shear strength and axial screw pullout force. A study on bovine cancellous bone, tested in pure shear, found the following relationship between shear strength, S , and apparent density, ρ , (Stone *et al.*, 1983):

$$S = 21.6\rho^{1.65} \quad (5.7)$$

Using the average data for the shear strength of the closed-cell PU foams used in this current study, obtained from the suppliers of the PU foams (Sawbones® Europe AB, Malmö, Sweden), a plot of log (shear strength) vs. log (apparent density) derived a similar relationship between shear strength and apparent density:

$$S = 21.5\rho^{1.42} \quad (5.8)$$

Similarly, the shear strength and apparent density of unicellular PU foam was found to have the following relationship (Chapman *et al.*, 1996):

$$S = 23.9\rho^{1.54} \quad (5.9)$$

Equations 5.7, 5.8 and 5.9 are all power law relationships with experimentally derived constants; they are all very similar and justify the use of PU foam, of various densities, to mechanically simulate the relative shear strength properties of bone. This is beneficial for screw pullout testing from low density PU foam, which would be able to model the shear strength of OP bone, as has been performed in this study.

5.6.4 Estimation of the Shear Strength of 0.09 g.cm^{-3} Open-Cell PU Foam

In §5.6.2, predictive values for axial screw pullout from 0.09 g.cm^{-3} PU foam could not be calculated because the shear strength of this foam was unknown and it is difficult to measure (because it is an open-cell foam). However, equation 5.8 could be used to calculate an estimated value for the shear strength of the 0.09 g.cm^{-3} open-cell PU foam; this was found to be 0.7 MPa.

Another method of estimating the shear strength of the 0.09 g.cm^{-3} open-cell PU foam is to use equations 5.5 and 5.6 and substitute F_S as the experimental mean axial pullout force (Figure 5.8 and Figure 5.9). Based on the cortical and cancellous screw mean axial pullout forces, the shear strength of the 0.09 g.cm^{-3} PU foam was found to be 0.04 MPa and 0.03 MPa respectively.

There is a marked difference in the above estimations of shear strength for the 0.09 g.cm^{-3} PU open-cell foam. A possible explanation is that equation 5.8 has been derived from the average material property data of closed-cell PU foams and so strictly cannot be applicable to open-cell PU foams. Similarly, equations 5.5 and 5.6 are based on calculating the shear failure force necessary to strip the internal threads formed in the PU foam; the internal threads in open-cell foam are likely to be more inconsistent and thus difficult to quantify when compared to closed cell PU foams. Therefore, the estimates of shear strength provided in this section should be treated with caution.

5.7 Conclusions

- Screw pullout force decreased as the PU foam density decreased (used to model increasingly OP cancellous bone in this study).
- In a model of very low density OP bone (0.09 g.cm^{-3} PU foam), screws inserted at 20° , 30° and 40° demonstrated larger pullout forces compared to screws inserted at 0° and 10° angles.
- For screws inserted at 10° , 20° , 30° and 40° , the resistance to pullout force was observed by compression of the PU foam material above the angled screw; clinically, this suggests that compressed OP bone is stronger than unloaded OP bone.
- In a normal cancellous bone model (0.32 g.cm^{-3} PU foam), screws inserted at 0° and 10° exhibited larger pullout forces compared to screws inserted at 20° , 30° and 40° angles; the results suggest that there is no benefit in placing screws at 40° in normal bone.

6. CAN A DOWEL BE USED INSTEAD OF A BONE SCREW?

6.1 Chapter Overview

In this chapter, a surgeon's idea for "screw" fixation without using a screw thread is tested. Section 6.2 introduces the basic idea, the study aim is described in §6.3 and the test is outlined in §6.4. Section 6.5 presents the results, which are discussed in §6.6 and summarised in §6.7.

6.2 Introduction

In August 2006, a meeting with a consultant orthopaedic surgeon prompted discussion of an idea that considered pedicle screw (PS) fixation without the use of screw threads, but using an interference fit within the pedicle instead (Mr A. Jackowski, personal communication). It was the surgeon's opinion that PS fixation is primarily achieved through a tight fit of the screw within the cortical-walled pedicle; believing that cancellous bone is not found consistently through the pedicle, but rather in clumps. A review of the literature has revealed that it is difficult to generalise on the bone structure, or morphology, of the human pedicle.

Roy-Camille *et al.* (1986) reported that the pedicle is a "cylinder of cortical bone surrounding a little cancellous bone." However, other early studies on thoracic and lumbar pedicle

morphology found that the pedicle is generally oval-shaped, but with a complicated, three-dimensional (3D) structure that resembles more of a teardrop shape upon closer inspection (Misenhimer *et al.*, 1989; Zindrick *et al.*, 1987). This is in agreement with Moran *et al.* (1989), whose measurements of thoracic and lumbar pedicles led them to conclude that the pedicles are less symmetric cephalad, but become more so caudal. Several researchers agree that the pedicle's cortical wall is thicker medially (to protect the spinal cord or cauda equina) than laterally (Karaikovic *et al.*, 1997; Kothe *et al.*, 1996; Panjabi *et al.*, 1997; Panjabi *et al.*, 2000). For thoracic pedicles specifically, these have been described as “teardrop or kidney shaped, with a laterally directed concavity and a medial convexity” (Panjabi *et al.*, 1997); where pedicle shape changes occur between different regions of the thoracic spine, as well as within the same region and even within the same pedicle (changes from posterior to anterior) (Kothe *et al.*, 1996). For lumbar pedicles, Hirano *et al.* (1997) characterised three regions of bone in the pedicle: cancellous, sub-cortical and cortical bone; the corresponding bone mineral densities were found to be lower in osteoporotic (OP) vertebrae than those in normal vertebrae.

Since the 1990s, an increased use of PS fixation in the cervical spine has encouraged several studies on cervical pedicle morphology. In their study of human cervical pedicles, Karaikovic *et al.* (1997) reported a small percentage (up to 4% at one vertebra level) of “solid” pedicles, comprised entirely of cortical bone. For the majority of pedicles that did have a medullary canal (assumed to be filled with cancellous bone), the surrounding cortical wall was found to have a non-uniform thickness; the medial cortex, toward the spinal cord, was twice as thick as the lateral cortex that protected the vertebral artery (Karaikovic *et al.*, 1997). This is in agreement with Panjabi *et al.* (2000), who also found that the cancellous core dimensions, not

the cortical wall thickness, increased with an increase in the external dimensions of cervical pedicles. Furthermore, Ebraheim *et al.* (1997) reported a larger pedicle height than the corresponding pedicle width for the lower cervical pedicles, which implies a general oval-shape for the cervical pedicles.

In this study, polyurethane (PU) foam was used to model cancellous bone (Patel *et al.*, 2008; Chapter 4) within the pedicle. A cancellous bone model was favoured, instead of a cortical bone model, because studies have shown that PS purchase is not always obtained within the cortical pedicle wall (Krag *et al.*, 1988; Misenhimer *et al.*, 1989). Furthermore, enough evidence exists to suggest that the pedicle is filled with more cancellous than cortical bone (Inceoglu *et al.*, 2005; Kothe *et al.*, 1996; Krag *et al.*, 1988; Misenhimer *et al.*, 1989; Moran *et al.*, 1989; Panjabi *et al.*, 2000; Santoni *et al.*, 2009), such that a screw is more likely to engage with cancellous bone in the pedicle.

6.3 Purpose of the Investigation

This study aimed to test a surgeon's idea (outlined at the beginning of §6.2) by determining the axial pullout force of a dowel, used to model the cortical screw from Chapter 5 except, without screw threads. The effect of pilot hole diameter on dowel pullout force was investigated. Dowel pullouts were performed using the cancellous bone models from Chapter 4, so that the results could be compared to the axial cortical screw pullout results in Chapter 5.

6.4 Materials and Methods

6.4.1 PU Foam Samples

The PU foams used in this study are as described in §5.4.1.

6.4.2 The Dowel

Based on the dimensions of the cortical screw used in Chapter 5, a 3 mm diameter dowel (Figure 6.1) was manufactured by a departmental technician (Mr L. Gauntlett). The dowel was made from an 8 mm diameter rod of Ti-6Al-4V standard alloy (Allegheny Technologies Limited, ATI Europe Distribution, Birmingham, UK); the rod conformed to the British Standard BS 7252-3:1997. The dimensions of the dowel can be found from the relevant engineering drawing in Appendix H.

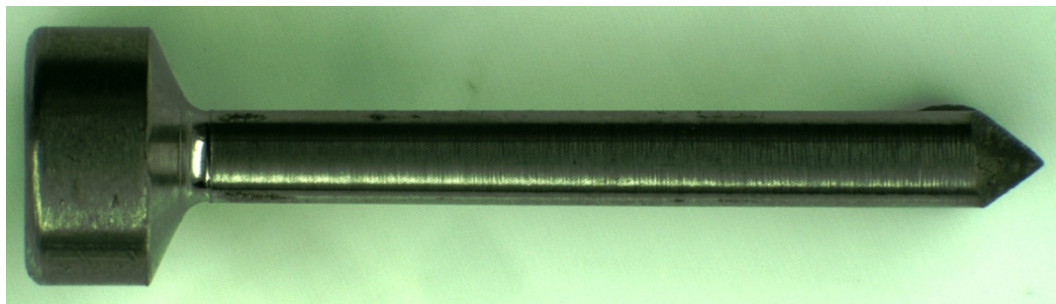


Figure 6.1 The 3 mm diameter dowel used for the axial pullout tests; it was modelled on the dimensions of the cortical screw used in Chapter 5.

6.4.3 Dowel Pullout Testing

The effect of pilot hole diameter on dowel pullout force was investigated. A single pilot hole of 1 mm, 1.5 mm, 2 mm or 2.5 mm diameter was drilled into a PU foam test block, which was then placed in a custom-made chamber, attached to a plate on the load cell of an ELF3300 materials testing machine (Bose Corporation, ElectroForce Systems Group, Minnetonka, MN, U.S.A.). The dowel was placed through a fixture (which was subsequently used for a pull out test) and inserted into the start of the pilot hole. The dowel was then compressed, using a flat plate, into a PU block at a displacement rate of 0.1 mm.s^{-1} (Figure 6.2). The dowel was inserted until its head met the surface of the pullout fixture; this procedure ensured that the dowel was repeatedly inserted under the same conditions.

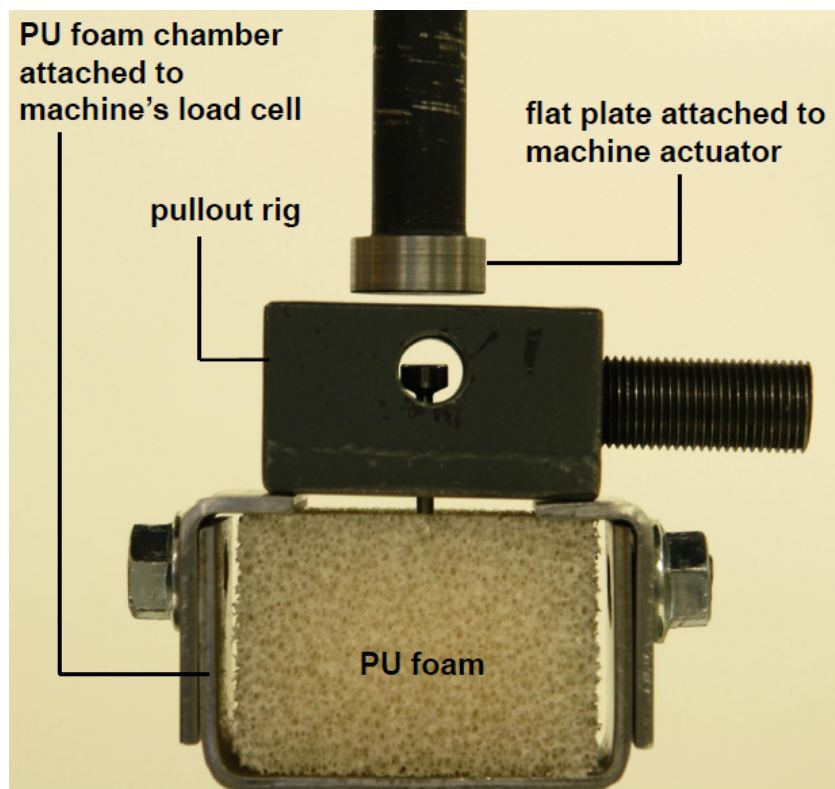


Figure 6.2 The dowel was inserted, under compression at a 0.1 mm.s^{-1} displacement rate, into the PU foam test block (0.09 g.cm^{-3} density in this case) via a custom-made pullout rig.

Following dowel insertion, the compression fixture was replaced by the top part of the pullout fixture (a 'sleeve' that fits within the chamber enclosing the dowel head), which was attached to the machine actuator. The 'sleeve' was lowered into position and the entire pullout fixture was locked by a pin, which combined the upper and lower parts of the pullout fixture (Figure 6.3). The dowel was then pulled from its head and along the axis perpendicular to the top surface of the test block (Figure 6.3); pullout was performed under displacement control at a rate of 0.1 mm.s^{-1} . Load and displacement values were recorded and the maximum load generated during dowel pullout was defined as the pullout force of the dowel. Six pullout tests were performed for each condition of pilot hole diameter (1 mm, 1.5 mm, 2 mm, 2.5 mm) and PU foam density (0.09 g.cm^{-3} , 0.16 g.cm^{-3} , 0.32 g.cm^{-3}). Following an analysis of results, additional tests were performed to further investigate the effect of dowel pullout force when using a pilot hole diameter very close to the core diameter of the dowel (3 mm). The extra tests were six dowel pullouts each, from 0.16 g.cm^{-3} and 0.32 g.cm^{-3} PU foams, using a 2.8 mm diameter pilot hole. The same dowel was used for all tests because of the comparatively low stiffness and strength of the PU foam when compared to the titanium alloy dowel (see §5.4.3 for further justification).

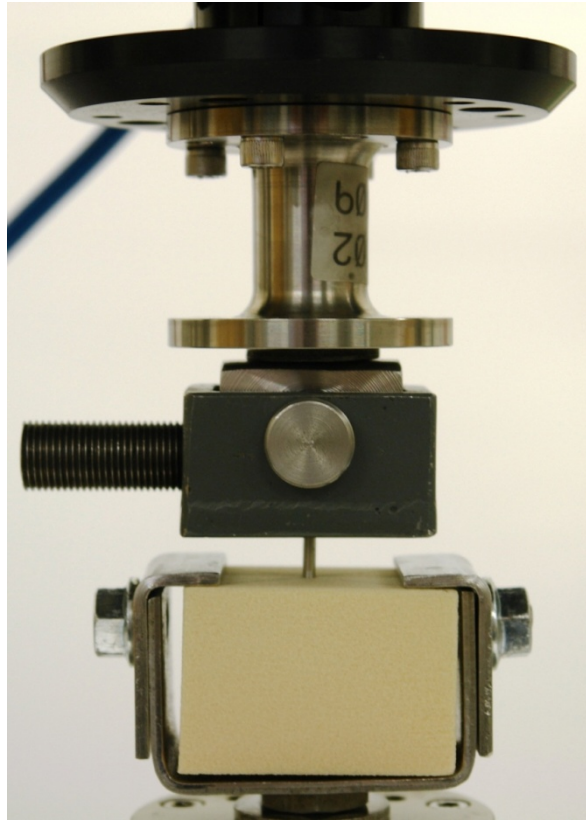


Figure 6.3 Axial pullout of the dowel from 0.16 g.cm^{-3} PU foam, used to model OP cancellous bone (Patel *et al.*, 2008; Chapter 4).

6.4.4 Statistical Analysis

Peirce's criterion (see Appendix F) was used to test for and exclude statistical outliers (Hawkins, 1980; Peirce, 1852; Ross, 2003). Statistical calculations were performed using MINITAB® Release 15 Statistical Software (Minitab Inc., Pennsylvania, USA). The significance level was set at 0.05 for all tests. Normality of the distributions was assessed using the Anderson-Darling test (Bland, 2000).

For data sets involving a 1 mm, 1.5 mm, 2 mm or 2.5 mm pilot hole diameter, data were compared using analysis of variance (ANOVA) and Tukey's Honestly Significant Difference multiple comparison tests (Bland, 2000). The ANOVA indicated whether there was a significant difference between test groups. The Tukey test identified between which groups there was a significant difference. Linear regression analysis was used to determine how dowel pullout force changes with the pilot hole diameter.

For the two data sets involving a 2.8 mm pilot hole diameter, data were compared using the two-sample t-test (Bland, 2000).

6.5 Results

6.5.1 Dowel Force-Displacement Curves

Figure 6.4 shows a typical force-displacement plot for dowel pullout from 0.09 g.cm^{-3} PU foam; the graph shows an initial rise in force that is subsequently sustained for the remainder of the dowel pullout test (note that the end forces on the graph account for the weight of the pullout rig, after full extraction of the dowel). Figure 6.4 indicates that 0.09 g.cm^{-3} PU foam provides little resistance to dowel pullout. This was expected to some extent; the foam has an open-cell structure, where any 'fixation' of the dowel would have already been compromised by pilot hole drilling, leading to structural foam damage around the dowel before pullout.

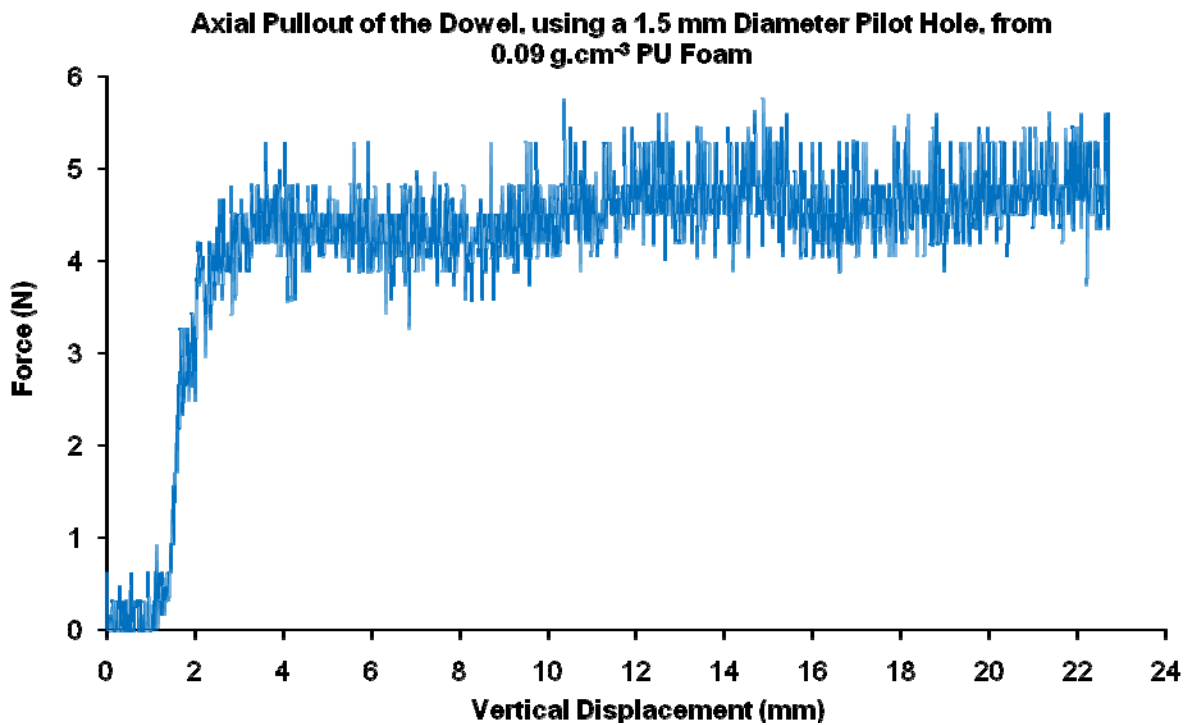


Figure 6.4 Example of a force-displacement plot obtained for dowel pullout from 0.09 g.cm⁻³ PU foam. Note that the end forces account for the weight of the pullout rig, after full extraction of the dowel.

The force-displacement plots for dowel pullout from 0.16 g.cm⁻³ and 0.32 g.cm⁻³ PU foams are exemplified by Figure 6.5. Unlike the 0.09 g.cm⁻³ PU foam, the higher density, closed-cell PU foams provided better resistance to dowel pullout; this is indicated by the steady decrease in pullout force after the maximum pullout force was attained (Figure 6.5).

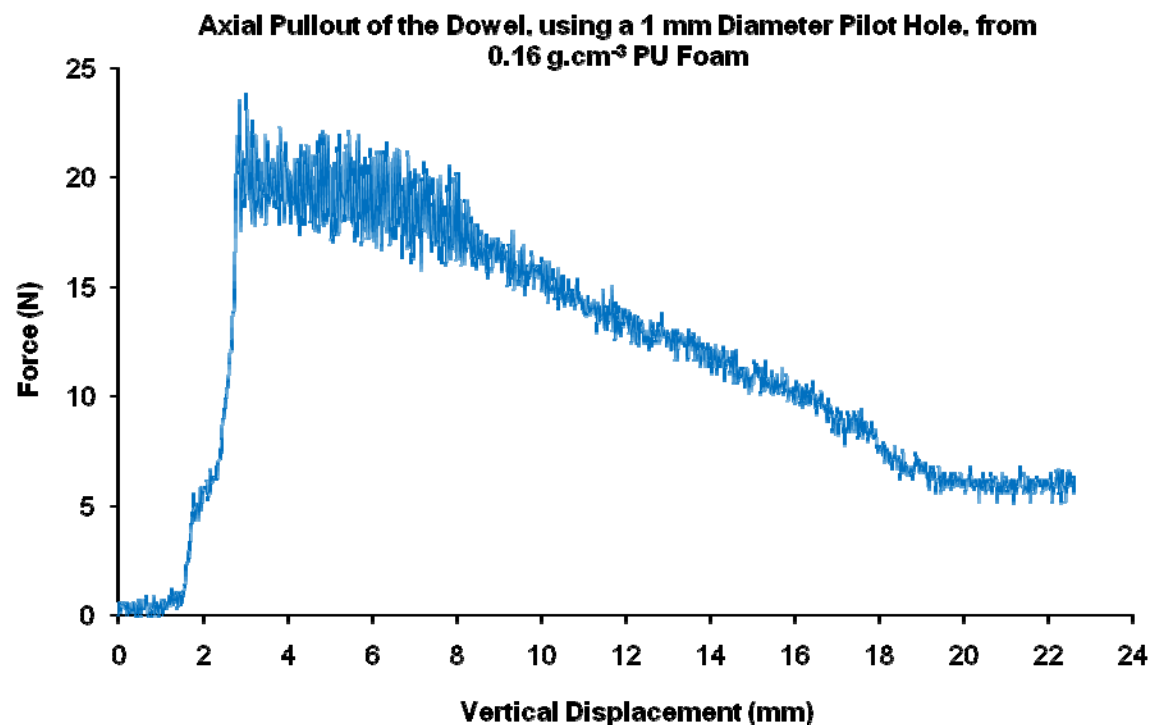


Figure 6.5 An example of the type of force-displacement plot obtained for dowel pullout from 0.16 g.cm⁻³ PU foam. Note that the end forces account for the weight of the pullout rig, after full extraction of the dowel. Similar plots were also obtained for dowel pullout from 0.32 g.cm⁻³ PU foam.

6.5.2 Axial Dowel Pullout Force

Figure 6.6 shows the mean values of dowel pullout force for the various pilot hole diameters.

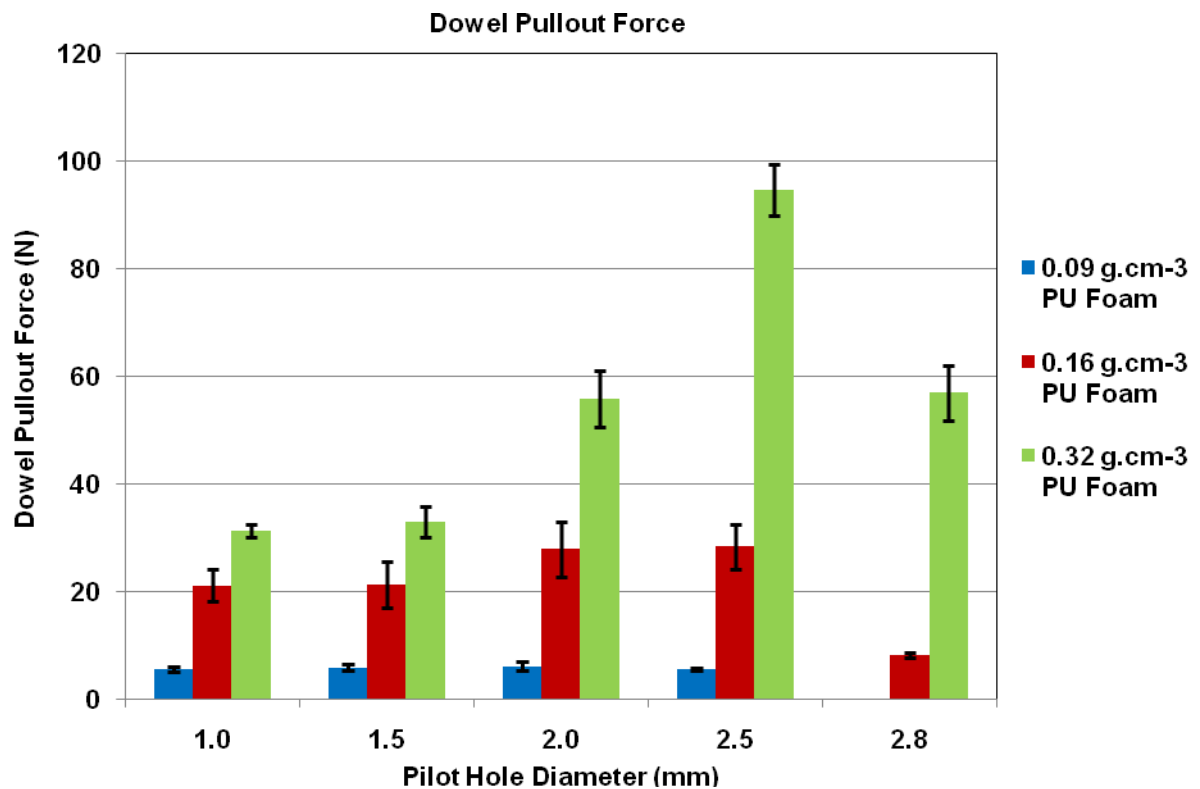


Figure 6.6 Bar chart to show the mean dowel pullout forces; the error bars represent the standard deviation for each data set. The mean represents up to six data points, depending on the number of excluded statistical outliers (approximately one in every two data sets). Dowel pullouts using a 2.8 mm pilot hole diameter in 0.09 g.cm⁻³ PU foam were not performed; this pilot hole diameter was investigated after an initial results analysis, which did not appear to show any useful information for 0.09 g.cm⁻³ PU foam.

All data sets were found to be normally distributed, except for the data set for dowel pullout from 0.09 g.cm⁻³ PU foam using a 2.5 mm diameter pilot hole ($p = 0.028$). Strictly, an ANOVA test assumes that the data comes from a normal population (Bland, 2000), but

because the dowel pullout data for 0.09 g.cm^{-3} PU foam did not appear to show any useful information (Figure 6.4 and Figure 6.6), the non-Normal data set (identified above) was included in the ANOVA test for completeness.

ANOVA and Tukey's Honestly Significant Difference multiple comparison tests showed a significant ($p < 0.05$) increase in dowel pullout force with increasing PU foam density. Significant differences ($p < 0.05$) were also detected for the dowel pullout force between the following pilot hole diameters: $1 \text{ mm} < 2 \text{ mm}, 2.5 \text{ mm}$; $1.5 \text{ mm} < 2 \text{ mm}, 2.5 \text{ mm}$; $2 \text{ mm} < 2.5 \text{ mm}$. There was no significant difference in the dowel pullout force between the 1 mm and 1.5 mm diameter pilot holes. Regression analysis showed no significant relationships between the mean dowel pullout force and pilot hole diameter, for all three PU foam densities. A significant difference ($p < 0.05$) was detected in the dowel pullout force from 0.16 g.cm^{-3} and 0.32 g.cm^{-3} PU foams, when a 2.8 mm pilot hole diameter was used.

6.6 Discussion

This study aimed to test a surgeon's idea that considered PS fixation without the use of screw threads, but using an interference fit within the pedicle instead (Mr A. Jackowski, personal communication). Figure 6.6 shows that the surgeon's idea is not supported by the results of this study; the dowel pullout forces were relatively small when compared to the axial pullout forces of the cortical screw (see Figure 5.8), on which the dowel dimensions were modelled. Particularly for the smaller pilot hole diameters, it is likely that the compaction of foam

material at the dowel-foam interface, during dowel insertion, caused the lower resistance to dowel pullout. Intuitively, the compaction of foam would be greatest when the dowel was inserted into a 1 mm diameter pilot hole; this might have provided an ‘easier’ path for the subsequent dowel pullout and therefore could explain the lowest dowel pullout forces recorded for this pilot hole diameter (Figure 6.6).

The surgeon’s idea may have some potential, if investigated further, for normal bone; dowel pullout force was greatest from 0.32 g.cm^{-3} PU foam (Figure 6.6). Also of interest is the increase in dowel pullout force with pilot hole diameter, up to 2.5 mm (Figure 6.6). An additional two dowel pullout tests, using a 2.9 mm pilot hole diameter in 0.32 g.cm^{-3} PU foam, were carried out to investigate whether dowel fixation can still be achieved when the pilot hole diameter is so close to the dowel’s core diameter (3 mm). These dowel pullout forces, not included in §6.5.2, were recorded as 6.4 N and 8.3 N. Therefore, all of the study results indicate that a threshold exists, at a point close to a 2.5 mm pilot hole diameter, above which the dowel pullout force starts to decrease.

Fixation of the dowel was heavily dependent on the host material; significant ($p < 0.05$) increases were detected in the dowel pullout force with increasing PU foam density. The benefit of using a dowel, instead of a screw, in OP bone is simple; there are no screw threads to cut through bone that is already fragile from above-normal porosity. However, this study has shown that, in a model of OP bone (Patel *et al.*, 2008; Chapter 4), there is no benefit in replacing a bone screw with one that has no screw thread, in an attempt to improve the fixation strength. The findings of this study are limited by the basic model used for the

pedicle; in reality the pedicle is a complex 3D structure (Kothe *et al.*, 1996; Misenhimer *et al.*, 1989; Panjabi *et al.*, 1997; Panjabi *et al.*, 2000). The author acknowledges that the pilot hole drill bit tolerances, dowel manufacturing tolerances and the lack of human bone specimens (and therefore the material properties of bone and its anatomical composition/structure) could all affect the outcome of this study. In addition, the surface roughness of the dowel was not measured; this affects the amount of frictional resistance to dowel pullout, which could be increased by using techniques such as grit blasting of the dowel. However, aside from testing a surgeon's idea, the study was designed to identify any general trends between pilot hole diameter and dowel pullout force.

Despite focusing on a dowel in this study, the results highlight the importance of the effect of pilot hole diameter on implant fixation, especially when using pilot hole diameters that are close to the core dowel/screw diameter. Recently, Tsai *et al.* (2009) acknowledged that the pilot hole was a function of PS pullout force in their comparative study of the predicted and experimental pullout force of conical and cylindrical PSs within PU foam. In a study of vertebral screws, Defino *et al.* (2009) showed that smaller pilot holes, but close to the core screw diameter, provided greater pullout forces in different materials, including PU foam, when compared to using pilot holes of an equal or wider diameter than the core screw diameter. Therefore, the pilot hole diameter is an important determinant of the screw pullout force.

6.7 Summary

A surgeon's idea of "screw" fixation, without using a screw thread, was tested by performing dowel pullouts in cancellous bone models (Patel *et al.*, 2008; Chapter 4). The dowel pullout forces were relatively small when compared to the axial pullout forces of the cortical screw (Chapter 5), on which the dowel dimensions were modelled. Therefore, the results of this study do not support the surgeon's idea. The effect of pilot hole diameter on dowel pullout force was also investigated. Generally, dowel pullout force increased with increasing pilot hole diameter, but this was not found to be statistically significant. A threshold appears to exist, close to a 2.5 mm pilot hole diameter (0.5 mm less than the dowel's core diameter), above which the dowel pullout force starts to decrease.

7. SCREW TOGGLING AND AXIAL PULLOUT IN NORMAL AND OSTEOPOROTIC CANCELLOUS BONE MODELS

7.1 Chapter Overview

In this chapter, screw pullout testing (Chapter 5) is taken a step further by performing screw toggling and subsequent axial screw pullout tests, in order to more closely approximate the physiological method of bone screw failure. Section 7.2 briefly introduces work that has already been reported in the literature, regarding *in-vivo* screw forces in the spine and biomechanical tests involving cyclically-loaded screws. Section 7.3 states the aim of this study and the method is described in §7.4. The results, presented in §7.5, are discussed in §7.6. Section 7.7 summarises the main conclusions from this study.

7.2 Introduction

In Chapter 5, pullout force was introduced as a measure of screw fixation strength (§5.2). In reality the loads imparted on bone screws are not entirely along the longitudinal axis of the screw; for example, pedicle screws (PSs) at the end of a vertebral fusion segment will be subjected to rotational and bending moments (Zindrick *et al.*, 1986). Early biomechanical studies of spinal implants, involving PSs with rods or plates, have shown that the PSs are subject to complicated cyclic forces that combine transverse bending and axial pullout loads

(Ashman *et al.*, 1989; Zand *et al.*, 1983); although the degree of bending will depend on how much the screw is fixed to the rod or plate (Ashman *et al.*, 1989). In a PS pullout study, Ruland *et al.* (1991) implied that axial pullout during flexion is the main mode of failure; this is in agreement with Wittenberg *et al.* (1991). Rohlmann *et al.* (1997; , 2000) measured the *in-vivo* loads transmitted through spinal fixators (a scaffold of rods, hooks and PSs in the spine) and determined that the main load components transmitted to the PS head consisted of an axial compressive force together with a flexion-bending moment.

The forces on a screw *in-vivo* can lead to screw loosening (Rohlmann *et al.*, 1995; Roy-Camille *et al.*, 1986); this is more likely if the screw is placed in weaker, osteoporotic (OP) bone (Burval *et al.*, 2007; Halvorson *et al.*, 1994; Hasegawa *et al.*, 1997; Okuyama *et al.*, 1993; Takigawa *et al.*, 2007; Tan *et al.*, 2004; Taniwaki *et al.*, 2003; Zindrick *et al.*, 1986). The loss of implant fixation through screw loosening can be detrimental to the stability of a fractured spine, particularly when fusion is desired (Inceoglu *et al.*, 2006; Ohlin *et al.*, 1994; Pihlajamaki *et al.*, 1997). Several researchers have addressed the problem of screw loosening by performing various biomechanical tests using cyclically loaded screws in healthy human vertebrae specimens, bovine vertebrae, ultra-high molecular weight polyethylene cylinders and polyurethane (PU) foam (of 0.32 g.cm^{-3} density) blocks (Al-Hadithi *et al.*, 2008; Barber *et al.*, 1998; Cunningham *et al.*, 1993; Ferrara *et al.*, 2003; Firoozbakhsh *et al.*, 1994; Inceoglu *et al.*, 2006; Law *et al.*, 1993; Lill *et al.*, 2000; Lotz *et al.*, 1997; McLachlin *et al.*, 2008; Sterba *et al.*, 2007; Wittenberg *et al.*, 1993; Wittenberg *et al.*, 1991; Zindrick *et al.*, 1986). The parameters studied included different screw insertion points and depths, augmented screws (with polymethylmethacrylate (PMMA), other bone cements, bushings or plates), screw diameter and pitch, different spinal devices (employing PSs) and the loading

rate. Fewer studies (Hasegawa *et al.*, 1997; Okuyama *et al.*, 1993; Santoni *et al.*, 2009; Takigawa *et al.*, 2007; Tan *et al.*, 2004; Taniwaki *et al.*, 2003; Zdeblick *et al.*, 1993) have reported cyclic loading on screws inserted in OP vertebrae; the effects of screw insertion torque, bone mineral density, screw insertion path, augmented PSs (with laminar hooks, wires or bone cement) and a novel PS (consisting of an internal screw and an outer sheath for spreading PMMA) were studied. Even fewer studies (Burval *et al.*, 2007; Hirano *et al.*, 1997) have considered screw failure, based on screw toggling and subsequent axial pullout, in OP vertebrae. However, the effect of screw toggling on the axial pullout force, in the context of OP bone, is still not clear. This needs to be further examined using an OP bone model that is free of the problems associated with using cadaveric specimens (see §2.7).

In this study, the forces on a screw *in-vivo* were simulated by toggling the screw in PU foam, which was used as an OP or normal cancellous bone model, depending on the PU foam density (Patel *et al.*, 2008; Chapter 4). To mimic screw toggling, the head of the screw was moved perpendicular to the axis of screw insertion; first upwards and then downwards.

7.3 Purpose of the Investigation

This study aimed to investigate whether screw toggling affects the axial screw pullout force. The cortical and cancellous screw types, used in Chapter 5, were toggled, in two of the cancellous bone models from Chapter 4, prior to axial pullout. The findings, which were compared to the axial (0°) screw pullout data from Chapter 5, may be informative for

clinicians dealing with screw loosening in their patients, particularly those with OP bone. For example, if screw toggling is not found to affect the axial screw pullout force, then the creation of a cavity in bone allows for it to be potentially filled with bone cement to enhance screw fixation in OP bone.

7.4 Materials and Methods

7.4.1 PU Foam Samples

The PU foams used in this study are as described in §5.4.1, with the exception of 0.09 g.cm⁻³ PU foam; screw toggling in this foam was not investigated because the foam's weak, open-cell structure (see Chapter 4) meant it was likely that the axial screw pullout force after toggling would be negligible.

7.4.2 Bone Screws

The cortical and cancellous bone screws used in this study are as described in §5.4.2.

7.4.3 Mechanical Testing

Pilot holes of 3.5 mm diameter, for the cancellous bone screw, and 3 mm diameter, for the cortical bone screw, were drilled into a PU foam test block before screw insertion. The test block was placed within a custom-made set of screw toggling apparatus (Figure 7.1), attached to a plate on the load cell of an ELF3300 materials testing machine (Bose Corporation, ElectroForce Systems Group, Minnetonka, MN, U.S.A.). A custom-made screw toggling fixture, attached to the machine's actuator, was then lowered to the point where it was aligned with the pilot hole on the test block. Each screw was inserted into the PU foam (Figure 7.1), via the toggling fixture, and was hand-tightened by a single investigator using a hexagonal key, until the head of the screw met the surface of the toggling fixture; this procedure ensured that all screws were inserted under the same conditions.

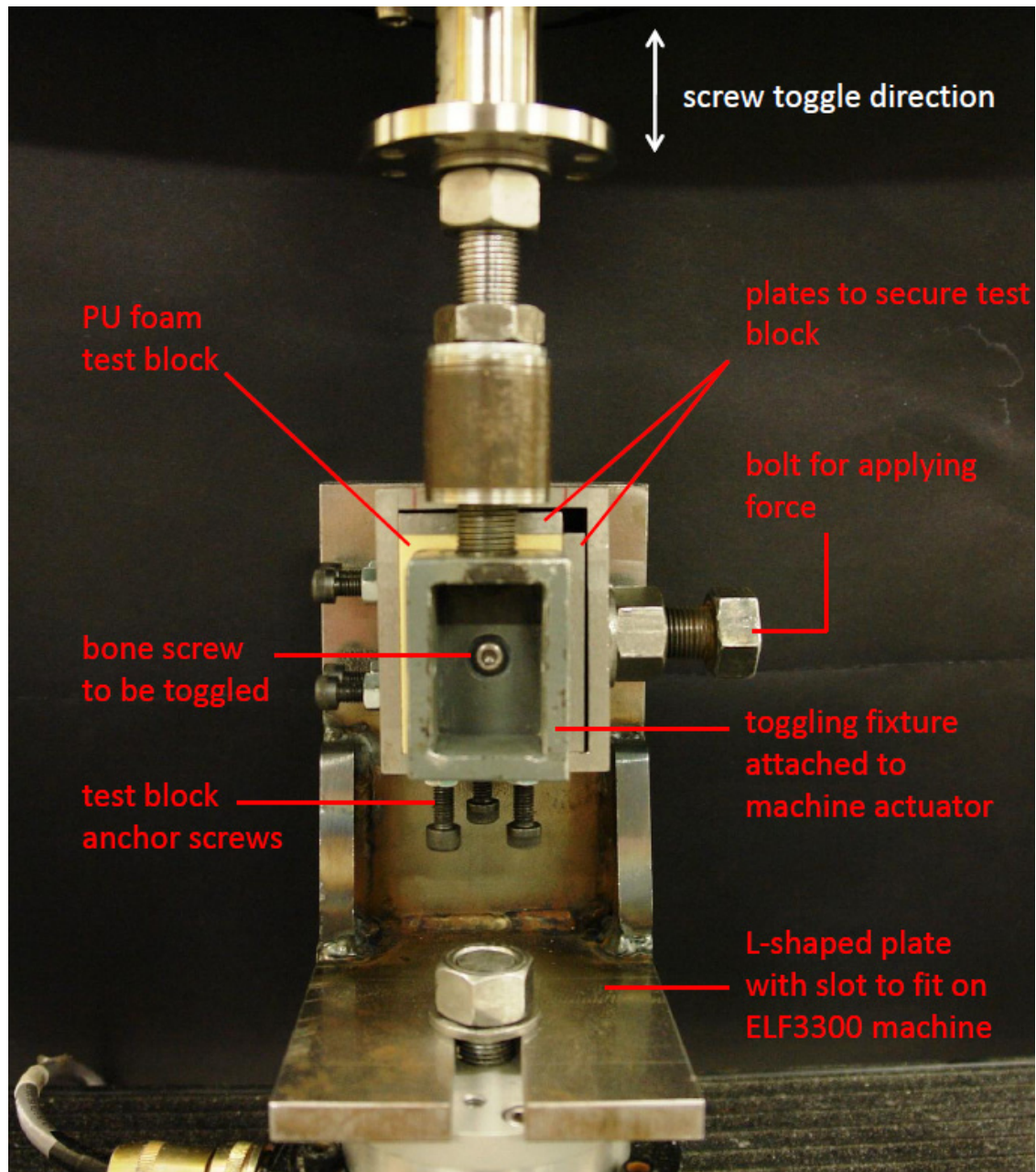


Figure 7.1 Screw toggle test set-up on the ELF3300 materials testing machine.

The toggling fixture was set to move ± 1 mm (Lotz *et al.*, 1997) under displacement control at a rate of 0.1 mm.s^{-1} ; each screw head was moved 1 mm upwards, then 2 mm downwards and 1 mm upwards again to the screw's original insertion axis (Figure 7.2). This method was chosen to make a clear void in the PU foam to mimic the situation of a screw loosening over

time; however, the void was not built up cyclically because only the end result was desired to perform axial screw pullout thereafter. Preliminary studies by Lotz *et al.* (1997) found that “displacements of 1 mm produced screw forces comparable with estimates of those generated during normal walking”, therefore a ± 1 mm displacement magnitude was chosen for screw toggling in the present study. Furthermore, screw toggling via load control is more difficult to perform because the entire test assembly could become unstable as the screw loosens; thus screw toggling via displacement control was chosen, as in previous studies (Burval *et al.*, 2007).

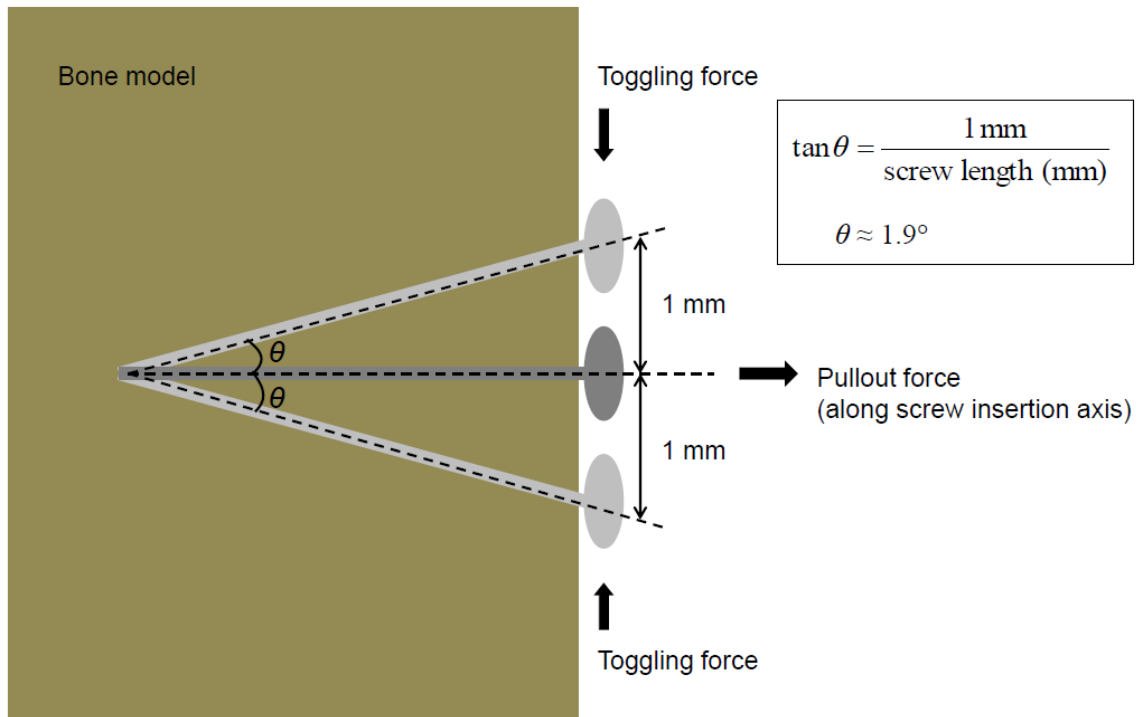


Figure 7.2 Illustration of the screw toggling and subsequent axial screw pullout tests performed in this study. Based on the cortical and cancellous screw lengths of 30 mm each, the screw toggling angle, θ , was estimated to be just below 2° . The illustration is based on the assumption that the screw pivoted at the screw tip following ± 1 mm displacement of the screw head; however, this cannot be claimed for certain (see §7.6).

After the screw had been toggled, the toggling apparatus was carefully removed from the testing machine to isolate the PU test block and the attached toggling fixture. The toggling fixture and PU foam assembly was then removed from the machine actuator, taking care not to damage the entire assembly, which was to undergo axial screw pullout. A rig changeover was required on the ELF3300 testing machine; a custom-made chamber was attached to a plate on the machine's load cell and the top part of a pullout fixture (a 'sleeve' that fits within the chamber enclosing the screw head) was attached to the machine actuator. The PU foam assembly was placed in the test chamber and the attached toggling fixture now served as the bottom part of a pullout fixture (Figure 7.3). The 'sleeve' was lowered into position and the entire pullout fixture was locked by a pin, which combined the upper and lower parts of the pullout fixture (Figure 7.3). The toggled screw was then pulled from its head and along the axis perpendicular to the top surface of the test block (Figure 7.3); pullout was performed under displacement control at a rate of 0.1 mm.s^{-1} . Load and displacement values were recorded and the maximum load generated during screw pullout was defined as the pullout force of the toggled screw.

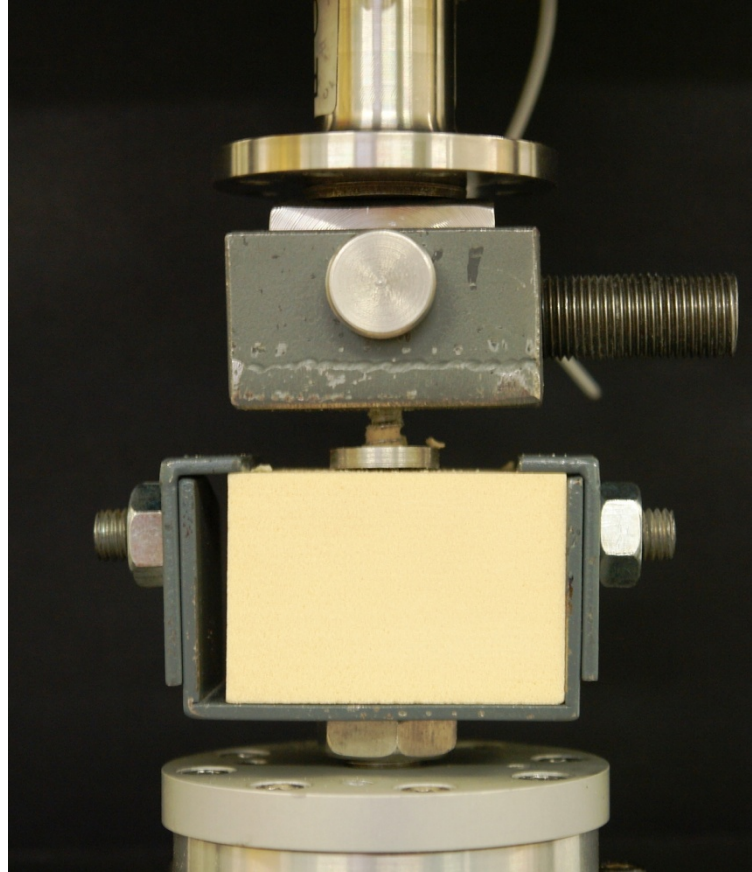


Figure 7.3 Axial screw pullout after ± 1 mm of screw toggling in 0.16 g.cm^{-3} (OP bone model) and 0.32 g.cm^{-3} (normal bone model) PU foam; a rig changeover was required between screw toggling and axial pullout.

Twelve screw toggling and axial pullout tests were performed for each bone screw type (cortical, cancellous) and PU foam density (0.16 g.cm^{-3} , 0.32 g.cm^{-3}). The same cortical and cancellous screw was used for all tests because of the comparatively low stiffness and strength of the PU foam when compared to the titanium alloy bone screws (see §5.4.3 for further justification).

The author acknowledges that the rig changeover employed during testing is a possible source of error, because it can cause unintended movement of the screw within the PU foam and,

thus, can affect the subsequent axial screw pullout force. However, the rig changeover was consistently employed across all screw tests and should, therefore, negate any bias. Other researchers (Burval *et al.*, 2007; Lotz *et al.*, 1997) have faced similar practicalities in the effective employment of screw toggling, prior to re-orientation of the test sample for axial screw pullout. With the assistance of a departmental technician (Mr C. Hingley), the screw toggle test rig (Figure 7.1) was not only designed to mimic loosening of a plate-screw construct in the spine, but also to utilise the axial screw pullout rig that already existed from the studies in Chapters 5 and 6.

7.4.4 Statistical Analysis

Peirce's criterion (see Appendix F) was used to test for and exclude statistical outliers (Hawkins, 1980; Peirce, 1852; Ross, 2003). Statistical calculations were performed using MINITAB® Release 15 Statistical Software (Minitab Inc., Pennsylvania, USA). The significance level was set at 0.05 for all tests. Normality of the distributions was assessed using the Anderson-Darling test (Bland, 2000). Axial (0°) screw pullout data from Chapter 5 were compared with the 'axial screw pullout after toggling' data, from the current chapter, using the two-sample t-test (Bland, 2000).

7.5 Results

7.5.1 Screw Force-Displacement Curves

Figure 7.4 shows a typical set of force-displacement curves generated from a screw toggling and subsequent axial pullout test. The hysteresis curve in the ‘Toggling’ plot is likely to have occurred from compaction of PU foam material as the screw head was toggled, first upwards and then downwards, by 1 mm in both directions. Using 0.16 g.cm^{-3} PU foam, the maximum toggling loads on the cortical screw head were $0.14 \pm 0.02 \text{ kN}$ (upwards) and $0.11 \pm 0.02 \text{ kN}$ (downwards). For 0.32 g.cm^{-3} PU foam, the corresponding maximum cortical screw toggling loads were $0.36 \pm 0.06 \text{ kN}$ and $0.32 \pm 0.05 \text{ kN}$. For the cancellous screw in 0.16 g.cm^{-3} PU foam, the maximum toggling loads were $0.15 \pm 0.02 \text{ kN}$ (upwards) and $0.13 \pm 0.02 \text{ kN}$ (downwards). In 0.32 g.cm^{-3} PU foam, the corresponding maximum cancellous screw toggling loads were $0.41 \pm 0.07 \text{ kN}$ and $0.35 \pm 0.06 \text{ kN}$. In all cases, the maximum screw toggling loads were less than the subsequent axial screw pullout forces. The ‘Toggling’ plots were also consistent with those published by Takigawa *et al.* (2007), in their study of PS toggling in OP human vertebrae.

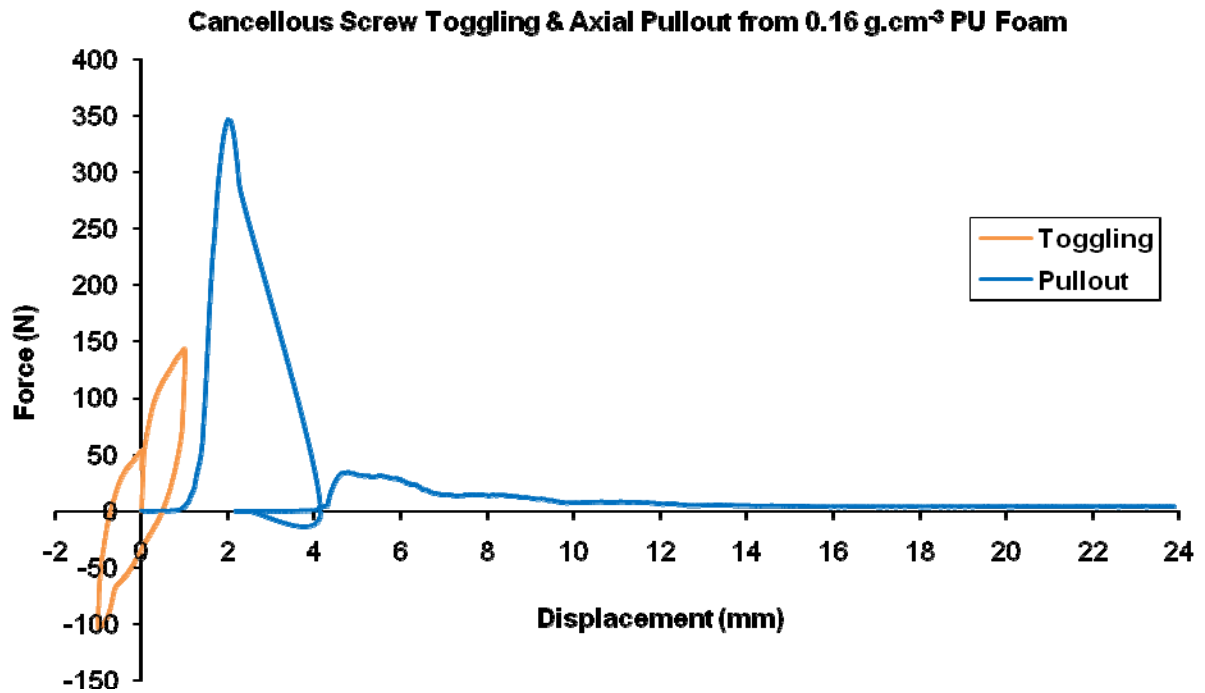


Figure 7.4 Example of the force-displacement curves obtained for the screw toggling and axial pullout tests; screw ‘failure’ was defined at the point of maximum screw pullout force. Note that the little loop at the foot of the first ‘Pullout’ peak was caused by the sudden movement of the screw (and the associated test rig) immediately after failure, when a slight rebound of the screw was commonly observed.

The ‘Pullout’ plots (Figure 7.4) were similar to the axial screw pullout plots, for 0.16 g.cm^{-3} and 0.32 g.cm^{-3} PU foam, from Chapter 5 (see Figure 5.6). Just as was found in Chapter 5 for axial screw pullout, the observed mechanism of failure for axial pullout of the toggled screws was stripping of the internal screw threads generated within the PU foam by screw insertion (Figure 7.3).

7.5.2 Axial Screw Pullout Force after Toggling

Table 7.1 shows the ‘axial screw pullout force after toggling’ data, which are compared to the axial screw pullout force data from Chapter 5. In both 0.16 g.cm⁻³ and 0.32 g.cm⁻³ PU foams, the cortical screw forces showed a significant ($p < 0.05$) difference between axial pullout only and axial pullout after toggling; this was not the case for the cancellous screw.

Table 7.1 Comparison of the mean screw pullout force \pm standard deviation, for axial pullout only (Chapter 5) and axial pullout after toggling. The asterisk (*) denotes a significant ($p < 0.05$) difference between the ‘axial screw pullout force’ and the ‘axial screw pullout force after toggling’ data groups.

PU foam density (g.cm ⁻³)	Bone screw type	Axial screw pullout force (kN)	Axial screw pullout force after toggling (kN)
0.16	Cortical	0.12 \pm 0.03	0.25 \pm 0.03 *
0.32	Cortical	1.11 \pm 0.05	1.02 \pm 0.10 *
0.16	Cancellous	0.37 \pm 0.03	0.34 \pm 0.02
0.32	Cancellous	1.15 \pm 0.06	1.15 \pm 0.24

7.6 Discussion

This study has investigated the effect of screw toggling on the axial screw pullout force of two types of screws, cortical and cancellous, from normal and OP cancellous bone models (Patel *et al.*, 2008; Chapter 4). Results have shown that a small amount of screw toggling (± 1

mm displacement) can significantly influence the axial pullout force of the cortical screw, but not the cancellous screw (Table 7.1).

In a study of cyclic loading on PSs prior to axial pullout, Burval *et al.* (2007) noted that screw toggling caused a 33% decrease in pullout force in OP lumbar vertebrae and caused a 20% drop in healthy, non-OP (normal) lumbar vertebrae, when compared to axial pullout without screw toggling. In the present study, toggling of the cortical screw caused a 208% increase in pullout force in an OP bone model and produced a 9% decrease in a normal bone model, when compared to axial pullout only. The corresponding effect of cancellous screw toggling was an 8% decrease in an OP bone model and no change to the pullout force in a normal bone model, although the larger standard deviation should be recognised for toggling in the normal bone model (Table 7.1). In their study of cyclic shear forces on the subsequent pullout force of bone screws, Firoozbakhsh *et al.* (1994) reported that the pullout force was highly reduced due to cyclic loading and that the loss was dependent on the screw thread design. The effect of thread design on screw pullout is discussed in §5.6.1 and can be described by the thread shape factor (T), which is discussed in §5.6.2.

Just how the axial cortical screw pullout force is affected by toggling is a point of interest, because toggling was found to increase the pullout force in 0.16 g.cm^{-3} PU foam but decrease the pullout force in 0.32 g.cm^{-3} PU foam (Table 7.1). The results suggest that cortical screw pullout is dependent on the structure of the host material; in this case, PU foam. Perhaps cortical screw toggling in 0.16 g.cm^{-3} PU foam, less dense and therefore more porous than 0.32 g.cm^{-3} PU foam, caused more foam compaction and subsequent resistance to axial

pullout than in the 0.32 g.cm^{-3} PU foam. This supports the idea, introduced in §5.6.1, that compression of 0.16 g.cm^{-3} PU foam, moreover compressed OP bone, can improve screw pullout resistance. To clarify this idea, foam compression in the present study is the result of screw toggling; in Chapter 5 foam compression is the result of increasing the screw pullout force, for a screw inserted at 10° , 20° , 30° or 40° to the axis of screw pullout.

Using young calf spines, Lill *et al.* (2000) performed axial pullout tests on cylindrical PSs and conical PSs (similar to the cortical and cancellous screws, respectively, used in the present study) with and without cyclic loading. In their study, the PSs were loaded cyclically in a cephalo-caudal direction, perpendicular to the screw axis, at 1 Hz (Lill *et al.*, 2000); load control was used to perform 5,000 screw cycles at $\pm 0.2 \text{ kN}$ (i.e. from the zero load position, the PS was displaced with a load of 0.2 kN cephalad and caudad, which is comparable to the present study). Lill *et al.* (2000) found that axial screw pullout force was significantly greater after cyclic screw loading than without such loading; the authors determined that this may be a result of bone compression around the centre of cantilever bending (from cyclic loading of the screw). In the present study, this could explain why cortical screw toggling significantly increased the axial pullout force in 0.16 g.cm^{-3} PU foam (Table 7.1) and also supports the idea outlined in the previous paragraph, for this PU foam. However, the majority of results in Table 7.1 do not support Lill *et al.* (2000)'s findings, possibly because the current study used a synthetic bone model, which does not replicate the viscoelastic properties of bone (Deligianni *et al.*, 1994; Pugh *et al.*, 1973). Nevertheless, Inceoglu *et al.* (2006) did report comparable results between PU foam and bovine bone, in their study of the axial cyclic behaviour of screw-bone interfaces.

The results of this study suggest that toggling of a conical screw (like the cancellous screw) behaves differently to that of a cylindrical screw (like the cortical screw). Toggling did not significantly influence the axial pullout force of the cancellous screw and this is likely due to its 4° taper angle. Krenn *et al.* (2008) proposed that a conical screw core displaces material to the wall of the pilot hole when inserted, leading to “wall thickening” or progressive compression of the surrounding material, which means that conical screws offer additional positive locking compared with cylindrical screws. During toggling, it is possible that part of the length of the cancellous (conical) screw was still locked in place, or had hardly moved, as the nearby compressed foam material resisted screw motion, such that the screw only became fully dislodged during subsequent axial pullout.

The simulation of physiologically loaded bone screws, using PU foam as a mechanical cancellous bone model (Patel *et al.*, 2008; Chapter 4), is difficult to perform in a clinically relevant manner. In this study, the screw toggle (± 1 mm displacement) created a model of a loosened bone screw, representing a somewhat extreme form of ‘bone’ compromise at the ‘screw-bone’ interface, which could reflect the end result of physiologic fatigue that can occur during the initial healing period after spinal fixation (Burval *et al.*, 2007; Cunningham *et al.*, 1993). Although a loosened screw model could be generated by cyclically loading a screw over an extended period of time, it is worth reminding the reader that, as discussed in §4.6, PU foam may not be a suitable bone model when energy dissipation is of concern and, therefore, cyclically-loaded screw tests should be avoided in this host material. Furthermore, the void in the PU foam test block, created by a single screw toggle to mimic a loosened bone screw, provides a more consistent ‘bony’ deficit to facilitate the comparison in pullout force of different bone screws.

It is important to account for screw toggling when analysing screw failure, especially in the pedicle. In Chapter 6 the complicated morphology of the pedicle was discussed (§6.2) and, although the pedicle is generally considered to provide a straight path for screw insertion, it is possible that there is pivoting at some instances of loading and that toggling is involved in the failure mechanism (Sterba *et al.*, 2007). Zindrick *et al.* (1986) described a “teeter-totter” motion in their cyclic screw tests, with the fulcrum or axis of rotation located within the pedicle. Law *et al.* (1993) demonstrated a rotational pattern of PS motion, with a fulcrum point at the base of the pedicle, creating a “butterfly-shaped” bony defect due to localised failure of the cancellous bone within the vertebral body and pedicle. These authors were able to improve PS performance under cyclic screw toggling by using a custom-made bushing, designed to bypass the cancellous bone lying between the screw and cortex of the pedicle (Law *et al.*, 1993); however a significant number of cadaveric specimens were damaged by insertion of the bushing, suggesting that this approach may not be clinically practical. In a study of augmented PSs, Tan *et al.* (2004) categorised the following patterns of motion for cyclically loaded screws: pure rotation, translation, rotation-translation and double rotation (involving out of plane motion).

In the present study, it is difficult to determine the exact screw motion within the PU foam during toggling; data were only recorded for ± 1 mm displacement of the screw head and, thus, it can only be assumed that this displacement corresponded to a maximum screw toggling angle of approximately 2° at the screw tip (Figure 7.2). The observed mechanism of failure for axial pullout of the toggled screws was stripping of the internal screw threads

within the PU foam; similar to axial screw pullout only, when the screw-foam interface failed in shear (§5.5.1). This similarity in observation suggests that the screw toggling force, relatively smaller than the subsequent axial pullout force, induced crushing (i.e. yield/failure) of the PU foam adjacent to the screw, but perhaps only primarily at the screw tip. It is difficult to define exactly where along the screw length failure of the PU foam material occurred because only displacement control of the screw head was performed; further study is required to locate and characterise the regions of PU foam yield and failure.

Future work could involve a cross-sectional analysis of the screw-foam interface after screw toggling, before considering subsequent axial pullout. In addition, a further study could incorporate screw toggling using larger displacements, as well as considering screw toggling along more than one axis to enhance the model of physiologic loading. However, a ± 1 mm displacement for screw toggling was purposely chosen in the present study because Lotz *et al.* (1997) found that “displacements of 1 mm produced screw forces comparable with estimates of those generated during normal walking.”

7.7 Conclusions

- The effect of screw toggling on the axial screw pullout force of two types of screws, cortical and cancellous, from normal and OP cancellous bone models (Patel *et al.*, 2008; Chapter 4) was investigated; results suggest that the effect is dependent on the screw thread design. The effect of thread design on screw pullout has been described by the thread shape factor (T), which is discussed in §5.6.2.
- Toggling (± 1 mm displacement perpendicular to the axis of screw insertion) of the cortical screw head significantly increased the axial screw pullout force, by more than a factor of two, in an OP bone model but significantly decreased (9%) the axial screw pullout force in a normal bone model; this supports the idea that compressed OP ‘bone’ (from screw toggling in this case) can improve screw pullout resistance.
- Toggling (± 1 mm displacement perpendicular to the axis of screw insertion) of the cancellous screw head did not significantly affect the axial screw pullout force in normal and OP bone models; this is likely to be due to the conical core screw design, which locks part of the length of the cancellous screw upon insertion.
- For the cortical and cancellous screws, the mean axial pullout forces after screw toggling were relatively small in the OP bone model when compared with the normal bone model.

8. SPINAL FUSION CAGE (STALIF TT™) PULLOUTS FROM NORMAL AND OSTEOPOROTIC CANCELLOUS BONE MODELS

8.1 Chapter Overview

In Chapter 2, §2.4 briefly introduced the STALIF TT™ ‘stand alone’ anterior lumbar interbody fusion cage with bone screws (see Figure 2.8). The current chapter considers a clinical application of bone screws by testing STALIF TT™ cages. The study was designed to combine and complete the work from Chapters 5 and 7, by performing pullout tests of the STALIF TT™ cage. Section 8.2 provides a brief description of the STALIF TT™ cage and the specific study aims are stated. Further details of the STALIF TT™ cage are provided in §8.3, the materials and methods section. The results, presented in §8.4, are discussed in §8.5 and concluded in §8.6.

8.2 Introduction

Much of the following information in this paragraph comes from the STALIF TT™ product literature, supplied by the company that developed the device, i.e. Surgicraft Ltd., Redditch, UK. Made from poly-ether-ether-ketone (PEEK), the STALIF TT™ cage is indicated for the replacement, partial vertebrectomy (cutting of a vertebra) and/or augmentation of a vertebral

body due to destruction by tumour or fracture. Therefore, the STALIF TT™ is intended to be used as a vertebral body replacement in the thoracolumbar spine (from T9 to L5). The STALIF TT™ cage has a large annular space for the placement of cancellous bone graft to promote spinal fusion. Following an anterior surgical approach to remove all or part of the intervertebral disc, the implant is inserted into the disc space and anchored into the adjacent vertebrae with three to four screws. The implant is designed primarily for ‘stand alone’ anterior lumbar interbody fusion that does not require an anterior plate or supplementary posterior instrumentation. The STALIF TT™ aims to restore alignment of spinal column, restore the height of the collapsed vertebral body and indirectly facilitates decompression of the surrounding nerve tissues. Osteoporosis is considered a relative contraindication for STALIF TT™ use, because it may limit the degree of fixation and correction; however, it is ultimately at the surgeon’s discretion whether the STALIF TT™ is inserted in osteoporotic (OP) bone. Furthermore, it is worth noting that many spinal fusions (including those using the STALIF TT™) are performed in fairly young, healthy patients (Christensen *et al.*, 2002; Freeman *et al.*, 2000); some of these patients could become OP later in life.

The purpose of this study was to quantify and compare the force required to pull out the STALIF TT™ cage from OP and normal human cancellous bone models (Patel *et al.*, 2008; Chapter 4). Individual STALIF TT™ screw pullouts have already been performed at various angles (i.e. the cancellous screw from Chapter 5), but it is not known how the screw configuration will behave in the STALIF TT™ cage.

8.3 Materials and Methods

8.3.1 STALIF TT™ Cages and Bone Screws

Twenty-four commercially available STALIF TT™ cages (product code STT36110-8LT, Surgicraft Ltd., Redditch, UK) (Figure 8.1a) were investigated in this pullout study. The STALIF TT™ cages were obtained in their sterilised form; there was no guarantee that the material properties of PEEK-OPTIMA® (from which the STALIF TT™ cage is made) would not change during the gamma-ray sterilisation process (Green and Schlegel, 2001), therefore it was important to perform the cage pullout tests using the final products. Each STALIF TT™ cage required a set of three cancellous bone screws: two ‘short’ screws (5.5 mm diameter \times 25 mm length) and one ‘long’ screw (5.5 mm diameter \times 30 mm length) (Figure 8.1b and Figure 8.1c). Both the ‘short’ and ‘long’ screws had a 4° core taper angle; the taper angles were measured from shadowgraphs (Zeiss MP320 Measuring Projector, Carl Zeiss Ltd., Rugby, Warwickshire, UK). Both screw types were manufactured from medical grade titanium alloy, Ti-6Al-4V, in accordance with the British Standard, BS 3531-5.3:1991, and are available commercially (Surgicraft Ltd., Redditch, UK).

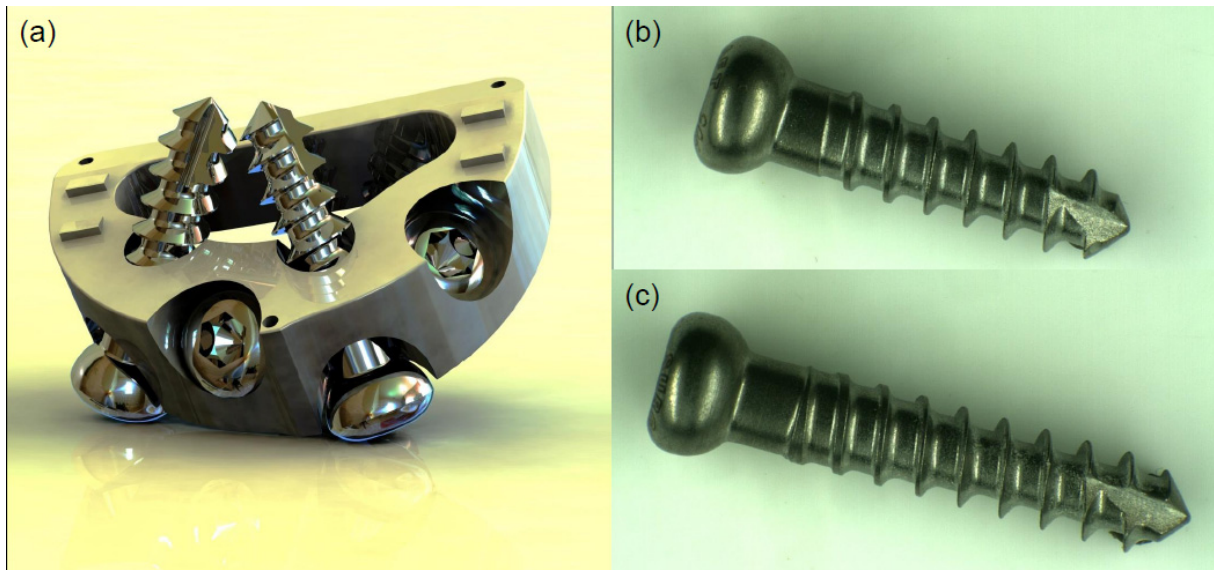


Figure 8.1 (a) A rendered image of a STALIF TT™ ‘stand alone’ anterior lumbar interbody fusion cage with cancellous screws, (b) a 5.5 mm diameter STALIF TT™ cancellous screw of length 25 mm, termed the ‘short’ screw. Two of these screws were used, for each STALIF TT™ cage, along with (c) a 5.5 mm diameter STALIF TT™ cancellous screw of length 30 mm, termed the ‘long’ screw. *Image ‘(a)’ kindly supplied by Surgicraft Ltd. (Redditch, UK).*

The STALIF TT™ cage can be fixed between lumbar vertebrae using a maximum of four ‘short’ screws (Figure 8.1a and Figure 8.1b). However, a three-screw (one ‘long’ and ‘two’ short) configuration is often adopted by surgeons using the STALIF TT™ cage, where the ‘long’ screw is placed in the opposite direction and in between the two ‘short’ screws (personal communication, Mr A. Fennell, International Sales Director, Surgicraft Ltd., Redditch, UK). Thus, only three holes are often used in the STALIF TT™ cage and they are all next to each other, leaving one hole spare on either the left-hand or right-hand side of the implant.

Table 8.1 summarises the ‘short’ and ‘long’ screw dimensions, which were determined from a series of measurements (seven and nine measurements for the ‘short’ and ‘long’ screw,

respectively, in accordance with the number of screw threads) obtained using a stereo microscope (Leica MZ9.5), digital microscopy camera (UEye 3.1MP) and imaging software (Omnimet Imaging Software version 9.0r3) (all available in the Buehler Centre of Excellence, School of Mechanical Engineering, University of Birmingham, UK); supplied by Buehler, Coventry, West Midlands, UK. The screw lengths were measured six times using digital vernier callipers (Fisher Scientific UK Ltd., Loughborough, Leicestershire, UK).

Table 8.1 ‘Short’ and ‘long’ STALIF TT™ cancellous bone screw measurements expressed as mean \pm standard deviation; the dimensions were determined from a series of measurements (see §8.3.1) and thus represent the average value for the entire length of the screw shaft. All measurements are defined in Figure 5.1a, except for the thread shape factor T , which is defined by equation 5.3 (see §5.6.2); the thread depth d was calculated using equation 5.4 (see §5.6.2). The standard deviations for d and T are estimated cumulative errors (Bevington, 1969). Dimensions are in mm, except for T , which is dimensionless.

Bone screw type	Major diameter, D_{maj}	Minor diameter, D_{min}	Thread length, L	Thread depth, d	Pitch, p	Thread shape factor, T
Ø 5.5 x 25 mm ‘short’ screw	5.57 ± 0.08	3.80 ± 0.53	18.13 ± 0.47	0.88 ± 0.27	2.31 ± 0.12	0.72 ± 0.22
Ø 5.5 x 30 mm ‘long’ screw	5.61 ± 0.06	3.89 ± 0.58	22.63 ± 0.08	0.86 ± 0.29	2.35 ± 0.05	0.71 ± 0.24

Each screw angle in the STALIF TT™ cage was measured as 48° to the horizontal (i.e. transverse) plane of the cage; this angle was measured with the assistance of Mr A. Saywell and Mr R. Beck in the Surface & Coordinate Metrology Laboratory, School of Mechanical Engineering, University of Birmingham, UK. The technique used to determine this screw angle measurement is described in Appendix G.

8.3.2 Polyurethane (PU) Foam Samples

The PU foams used in this study are as described in §5.4.1, with the exception of 0.09 g.cm⁻³ PU foam; cage pullouts from this foam were not investigated because the foam's open cell structure meant it was likely that the cage pullout force would be negligible.

The PU foam samples were further prepared by milling (Adcock-Shipley 1ES Vertical Milling Machine, Leicester, UK) a 4° declination (in agreement with the top and bottom surfaces of the STALIF TT™ cage) on the PU block surface that would make contact with the cage (Figure 8.2a); a digital protractor (Lucas AngleStar® DP45, Lucas Sensing Systems Inc., Hampton, Virginia, USA) was used to accurately mill the 4° declination. Wet and dry sandpaper (Norton T489 P400 HC, RS Components Ltd., Northamptonshire, UK) was used to finish the milled PU foam surface (Figure 8.2b).

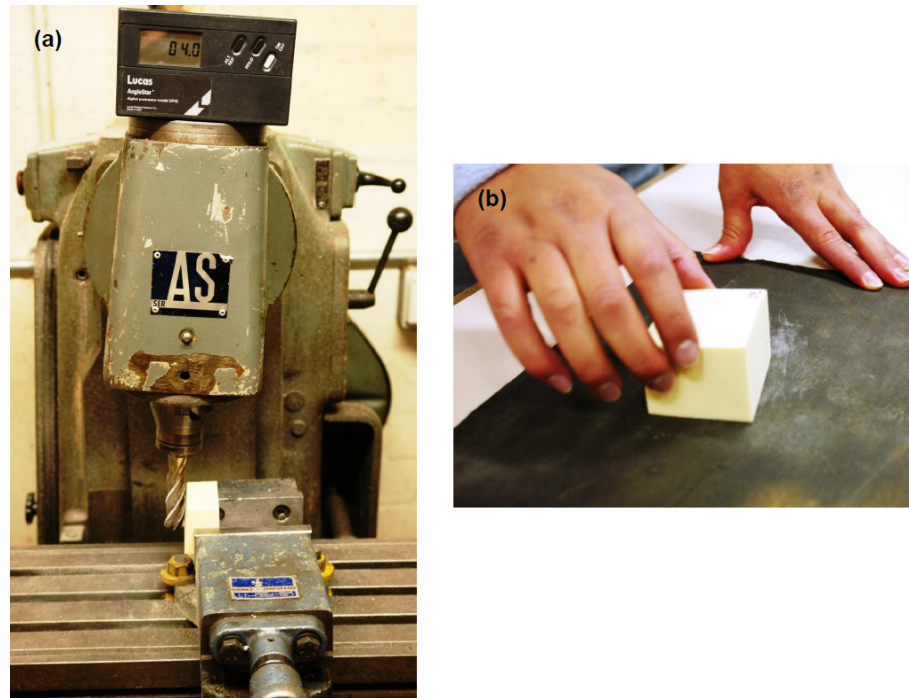


Figure 8.2 PU foam preparation by (a) milling each sample at a 4° angle to the vertical axis and (b) using wet and dry paper to even out the milled surface, ready for assembly with the STALIF TT™ cage.

8.3.3 STALIF TT™ Cage Assembly

The various stages of the STALIF TT™ cage assembly to PU foam are illustrated in Figure 8.3; the entire assembly was designed to mimic screw fixation of the STALIF TT™ cage between two lumbar vertebrae, comprised of either OP bone (modelled using 0.16 g.cm^{-3} PU foam) or normal bone (modelled using 0.32 g.cm^{-3} PU foam) (Patel *et al.*, 2008; Chapter 4). Prior to screw insertion, 3.5 mm diameter pilot holes were drilled using a battery operated drill (Bosch GSB 18VE-2, Price Tool Sales Ltd., Birmingham, UK).

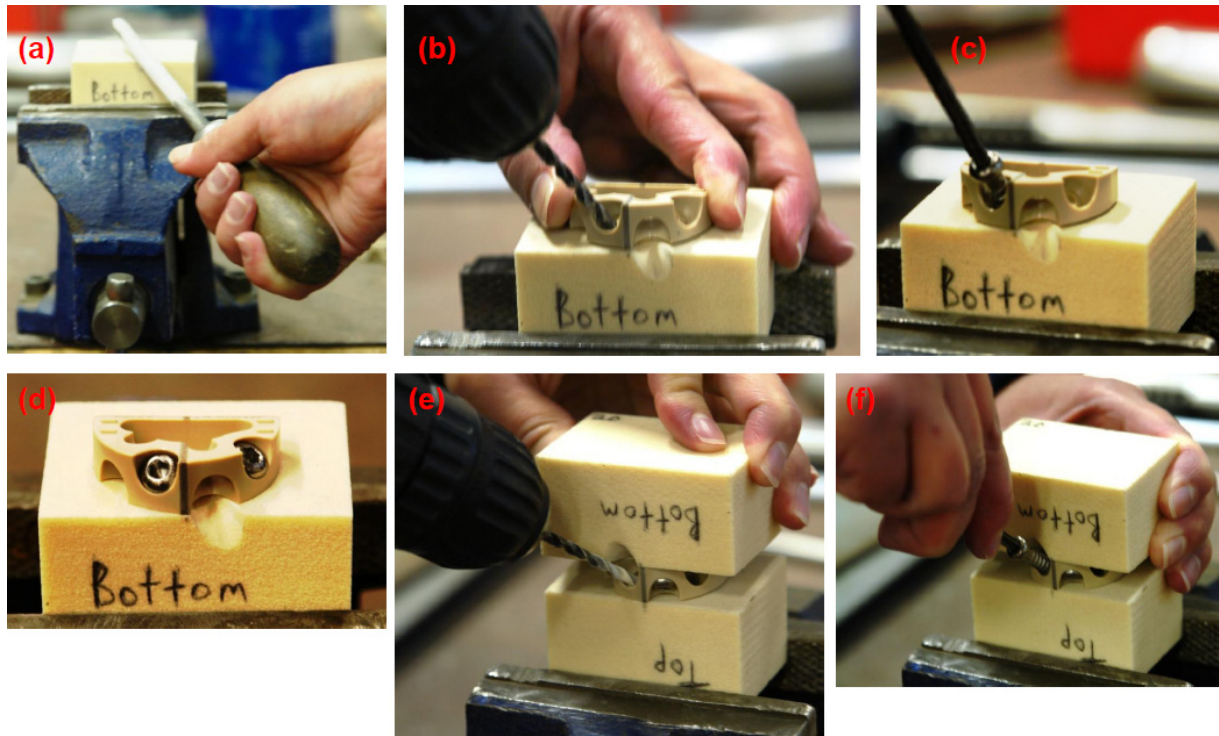


Figure 8.3 The various stages of the STALIF TT™ cage assembly: (a) using a rounded file to create a clearance channel for screw insertion, (b) drilling a 3.5 mm diameter pilot hole, for the ‘short’ screws, using the STALIF TT™ cage holes as a guide, (c) screw insertion with a hexagonal key, (d) two ‘short’ screws inserted in one half of the assembly, (e) drilling a 3.5 mm diameter pilot hole for the ‘long’ screw and (f) insertion of the ‘long’ screw. Vertical alignment was achieved by marking the measured centre of each front edge of each PU test block and aligning these marks with the black vertical line of the STALIF TT™ cage [photo (e)].

8.3.4 STALIF TT™ Cage Pullout Testing

In this study, the loads were not representative of spinal loading *in-vivo* (see §2.3.2); the aim of the study was to determine the strength of screw fixation for the STALIF TT™ cage. Each cage assembly was placed in a custom-made pair of test chamber rigs (Figure 8.4), one attached to the actuator and the other attached to a plate on the load cell, on an ELF3300 materials testing machine (Bose Corporation, ElectroForce Systems Group, Minnetonka, MN,

U.S.A.). The cage assembly was then pulled along the vertical axis, under displacement control, at a rate of 0.1 mm.s^{-1} . Load and displacement values were recorded and the maximum load generated during cage pullout was defined as the pullout force of the cage. Twelve pullout tests were performed for each condition of PU foam density (0.16 g.cm^{-3} , 0.32 g.cm^{-3}). To eliminate any potential bias in the results, six of the twelve tests were performed with the 'long' screw placed in the hole immediately to the left of the STALIF TT™ cage midline, whilst the other six tests were performed with the 'long' screw placed in the hole immediately to the right of the cage midline. The STALIF TT™ cages and screws were not re-used during testing.

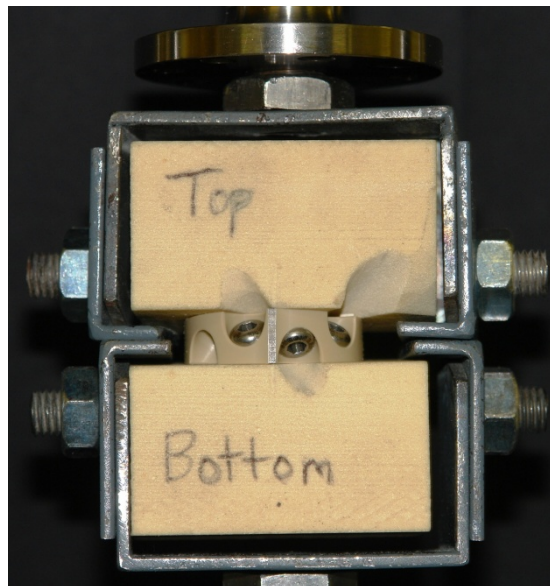


Figure 8.4 STALIF TT™ cage pullout test set-up in the ELF3300 materials testing machine.

8.3.5 Statistical Analysis

Peirce's criterion (see Appendix F) was used to test for and exclude statistical outliers (Hawkins, 1980; Peirce, 1852; Ross, 2003). Statistical calculations were performed using

MINITAB® Release 15 Statistical Software (Minitab Inc., Pennsylvania, USA). The significance level was set at 0.05 for all tests. Normality of the distributions was assessed using the Anderson-Darling test (Bland, 2000). Data were compared using the two-sample t-test (Bland, 2000).

8.4 Results

8.4.1 Mode of STALIF TT™ Cage Pullout Failure

In 0.16 g.cm⁻³ PU foam, an OP bone model, failure of the STALIF TT™ cage fixation either occurred by pullout of the ‘long’ screw or the two ‘short’ screws (Figure 8.5); although ‘long’ screw pullout was observed the most (i.e. nine times out of the overall eleven STALIF TT™ cage pullout tests from this foam). Two mechanisms of failure were identified during the pullout of each ‘long’ screw: (1) on the outer side of the screw, stripping of the internal screw threads generated within the PU foam by screw insertion was observed and (2) on the inward side of the screw (facing the STALIF TT™ cage), fragments of PU foam were found to be stuck to the screw threads (Figure 8.5a). Pullout of each set of two ‘short’ screws exhibited a similar mechanism of failure, but a larger fragment of PU foam was dislodged from the test block, between the two screws and at the proximal end of both screws (Figure 8.5b), compared to STALIF TT™ cage failure by ‘long’ screw pullout.

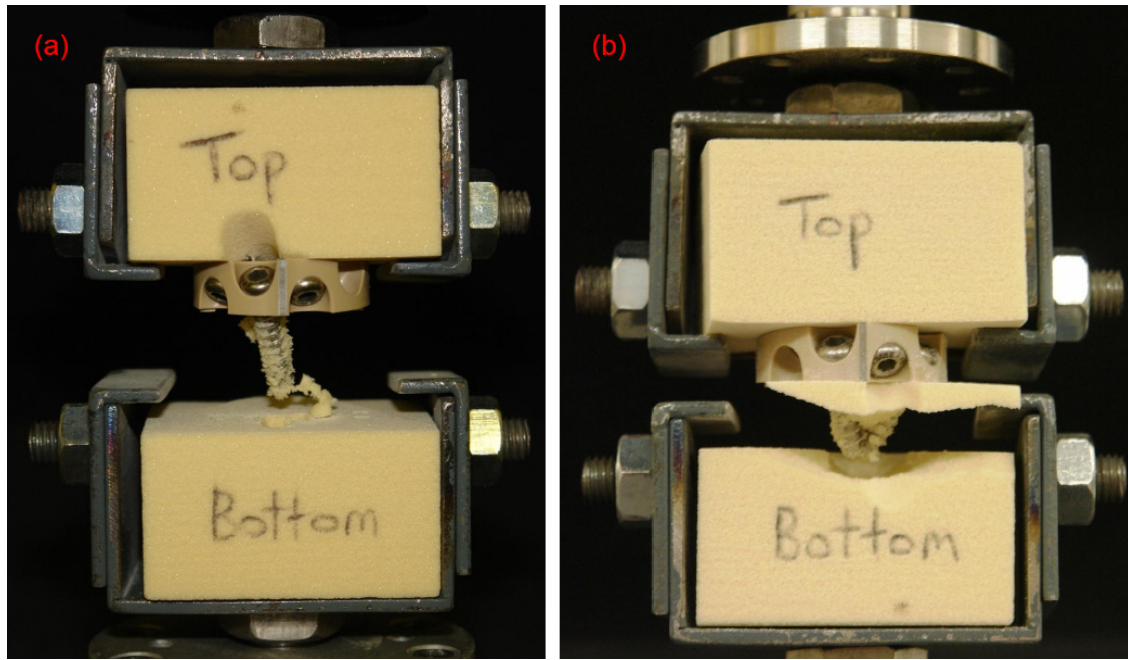


Figure 8.5 Failure of STALIF TT™ cage fixation by pullout of (a) the ‘long’ screw and (b) the two ‘short’ screws, from 0.16 g.cm^{-3} PU foam used to model OP bone (Patel *et al.*, 2008; Chapter 4).

In 0.32 g.cm^{-3} PU foam, a normal bone model, failure of the STALIF TT™ cage fixation either occurred by pullout of the ‘long’ screw or the two ‘short’ screws (Figure 8.6); however, unlike in 0.16 g.cm^{-3} PU foam, pullout of the two ‘short’ screws was observed the most (i.e. nine times out of the overall twelve STALIF TT™ cage pullout tests from this foam). The modes of failure were similar to those described in the previous paragraph, although the amount of fragmented PU foam stuck to the ‘long’ and ‘short’ screws (depending on the type of screw failure) was observed to be greater in 0.32 g.cm^{-3} PU foam (Figure 8.6), compared to 0.16 g.cm^{-3} PU foam.

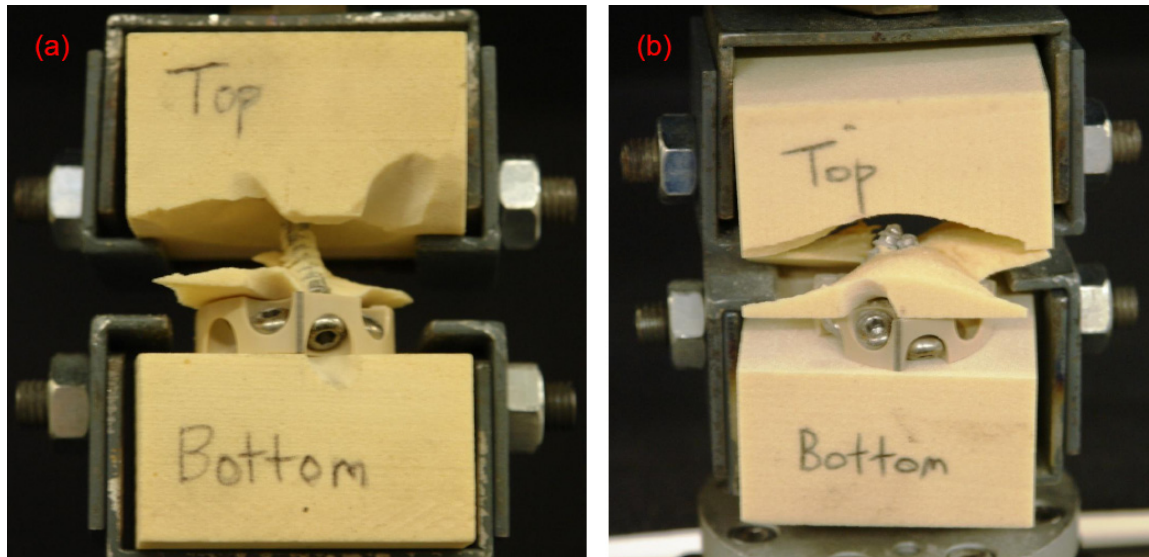


Figure 8.6 Failure of STALIF TT™ cage fixation by pullout of (a) the ‘long’ screw and (b) the two ‘short’ screws, from 0.32 g.cm^{-3} PU foam used to model normal bone (Patel *et al.*, 2008; Chapter 4).

8.4.2 Force-Displacement Curves for STALIF TT™ Cage Pullouts

Figure 8.7 shows typical force-displacement curves for STALIF TT™ cage pullout from 0.16 g.cm^{-3} PU foam. The maximum screw (either the ‘long’ screw or two ‘short’ screws combined) pullout force was defined as the STALIF TT™ cage pullout force, or point of failure; values were found to be similar regardless of whether failure had occurred by pullout of the ‘long’ screw or two ‘short’ screws. The ‘long’ screw demonstrated a gradual decrease post screw failure, thus providing better resistive force to pullout (after failure) than the two ‘short’ screws, which showed a relatively abrupt decline in force after failure (Figure 8.7). For cage failure by pullout of the two ‘short’ screws, two pronounced peaks were identified from the force-displacement curve (Figure 8.7); these are likely to correspond to the individual failure points of the two ‘short’ screws.

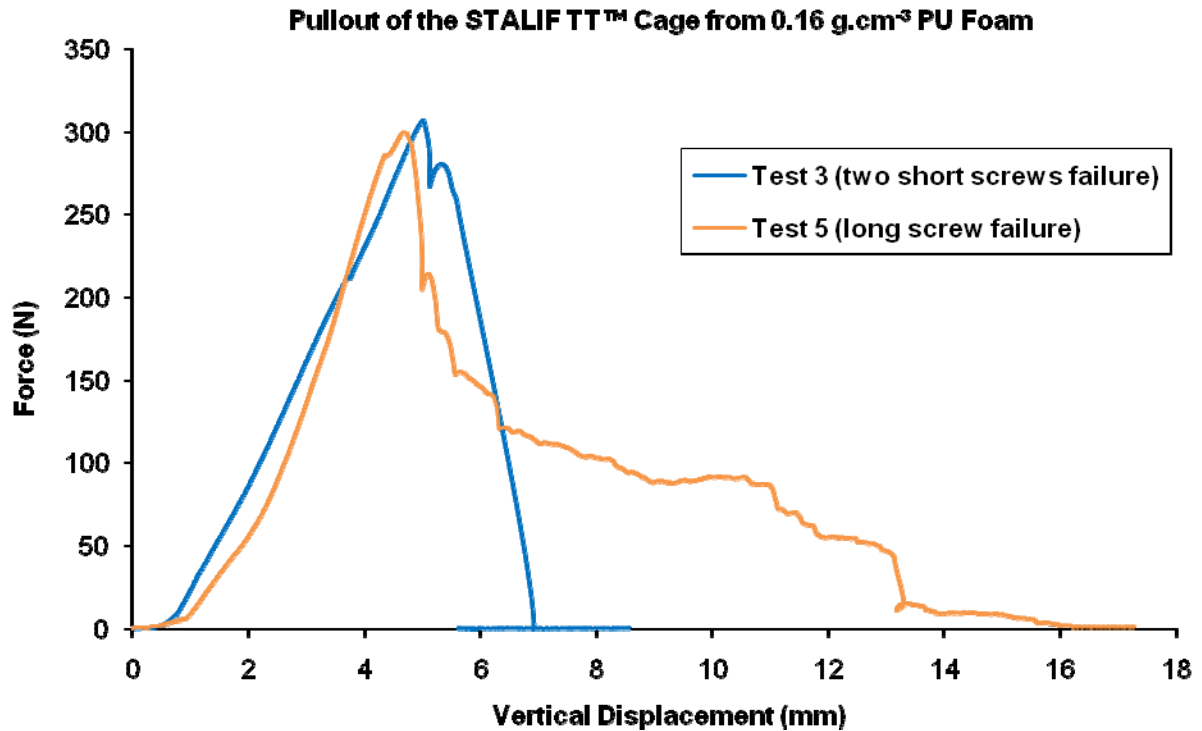


Figure 8.7 Examples of the force-displacement curve obtained for STALIF TT™ cage failure by pullout of the two ‘short’ screws (Test 3) or one ‘long’ screw (Test 5) from 0.16 g.cm⁻³ PU foam, used to model OP bone (Patel *et al.*, 2008; Chapter 4).

Typical force-displacement curves for STALIF TT™ cage pullout from 0.32 g.cm⁻³ PU foam are shown in Figure 8.8; whilst the two curves portray a large difference between the maximum cage pullout force from ‘long’ screw pullout and that from two ‘short’ screws pullout, the overall cage pullout forces were found to be similar for this PU foam. The shape of the force-displacement curves were also comparable (Figure 8.8), despite the different screw failures. This could be explained by the structure of the 0.32 g.cm⁻³ PU foam, which provided greater resistance up to the cage pullout force, compared to the 0.16 g.cm⁻³ PU foam, but was unable to provide as much of a compressive resistive force, as shown by the ‘long’ screw in 0.16 g.cm⁻³ PU foam, after the maximum cage pullout force was attained (Figure 8.7

and Figure 8.8). The two prominent peaks in Figure 8.8 are likely to correspond to the individual failure points of the two ‘short’ screws.

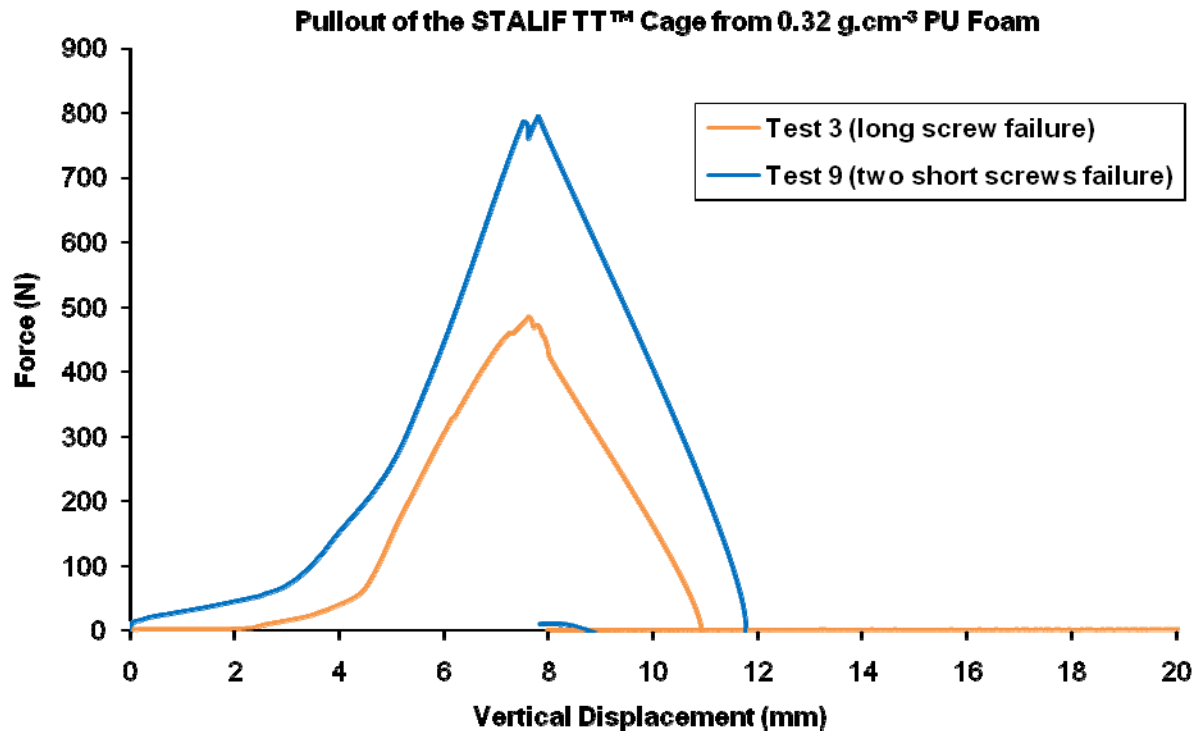


Figure 8.8 Examples of the force-displacement curve obtained for STALIF TT™ cage failure by pullout of the two ‘short’ screws (Test 9) or one ‘long’ screw (Test 3) from 0.32 g.cm⁻³ PU foam, used to model normal bone (Patel *et al.*, 2008; Chapter 4).

8.4.3 STALIF TT™ Cage Pullout Force

Figure 8.9 and Figure 8.10 show values of STALIF TT™ cage pullout force from 0.16 g.cm⁻³ and 0.32 g.cm⁻³ PU foams respectively. All data sets were found to be normally distributed. Significant differences ($p < 0.05$) were detected between the cage pullout forces from 0.16 g.cm⁻³ and 0.32 g.cm⁻³ PU foams. For each density of PU foam (0.16 g.cm⁻³, 0.32 g.cm⁻³), no significant differences were detected between the cage pullout forces from: (i) using two different screw configurations (‘long’ screw right and upwards, ‘long’ screw left

and downwards), or from (ii) the mode of cage pullout failure ('long' screw failure, two 'short' screws failure).

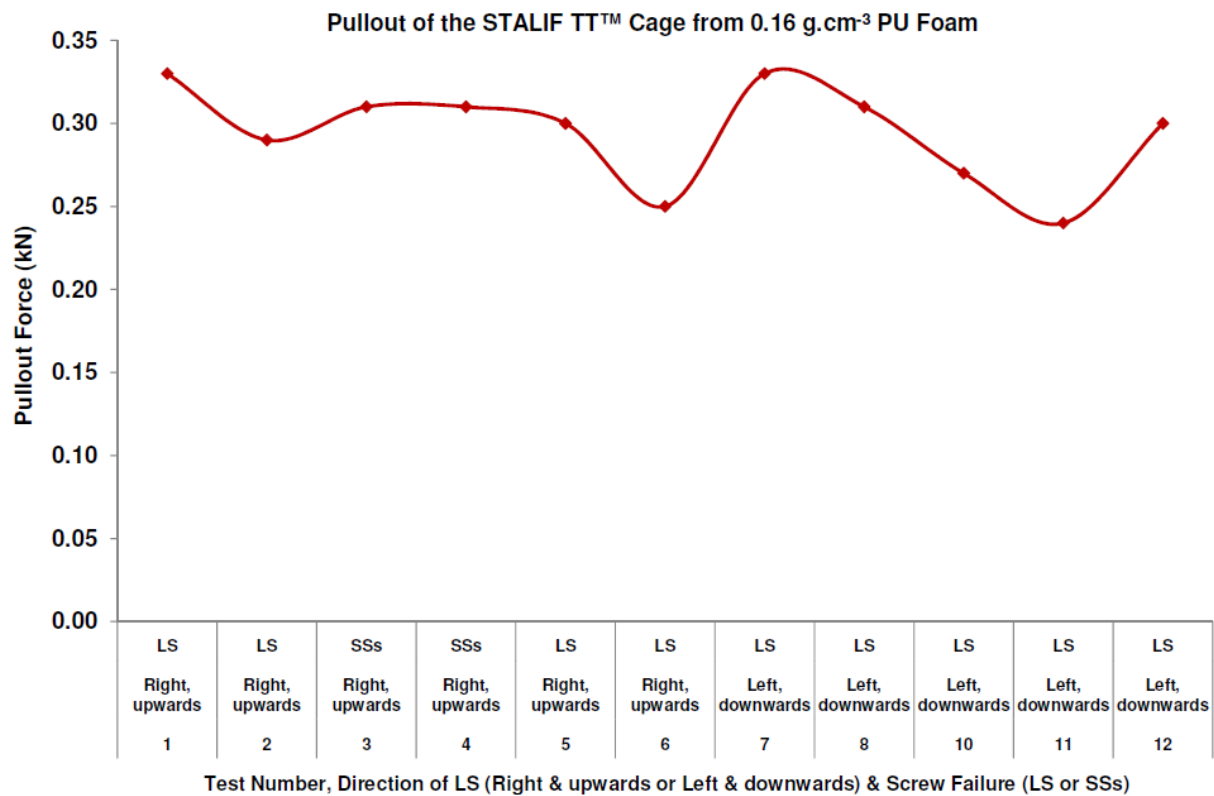


Figure 8.9 Pullout force of the STALIF TT™ cage from 0.16 g.cm⁻³ PU foam, used to model OP bone (Patel *et al.*, 2008; Chapter 4). The mean cage pullout force \pm standard deviation was 0.30 ± 0.03 kN. Note that Test 9 was excluded as a statistical outlier under Peirce's criterion (Hawkins, 1980; Peirce, 1852; Ross, 2003). LS = 'long' screw; SSs = 'short' screws.

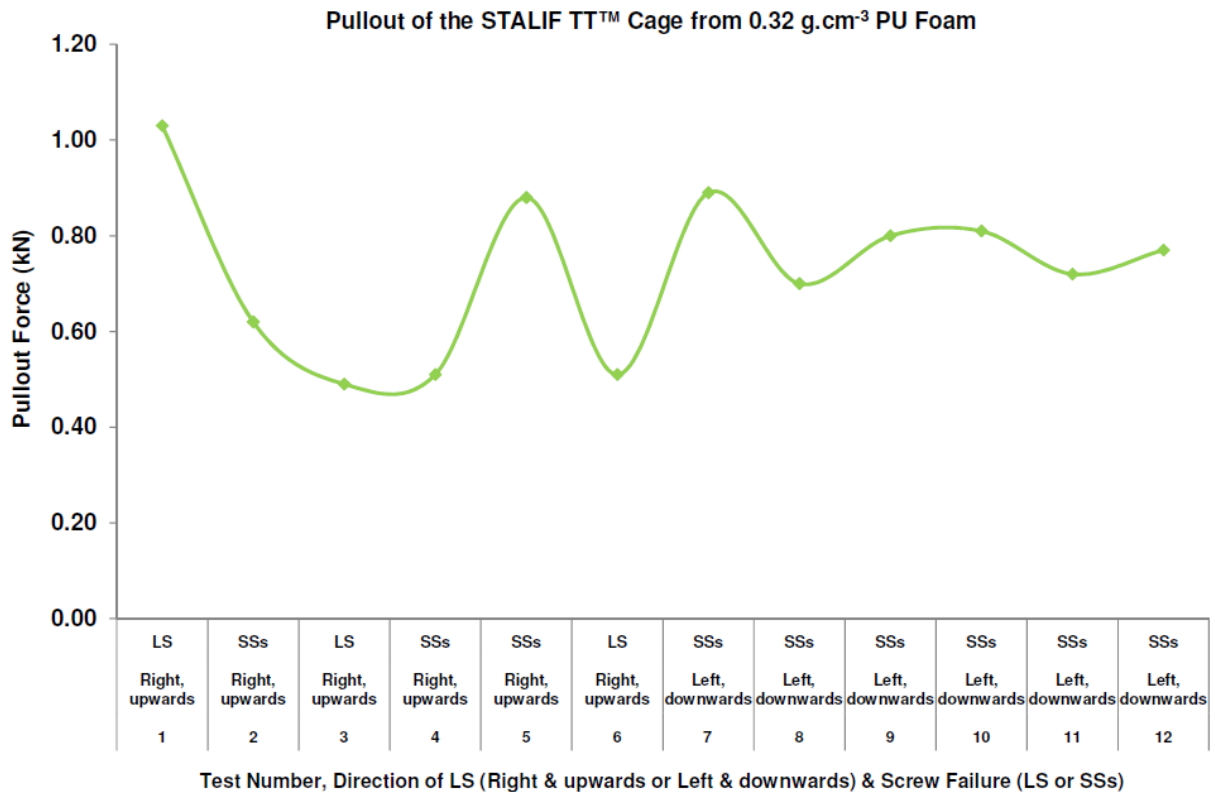


Figure 8.10 Pullout force of the STALIF TT™ cage from 0.32 g.cm⁻³ PU foam, used to model normal bone (Patel *et al.*, 2008; Chapter 4). The mean cage pullout force \pm standard deviation was 0.73 ± 0.17 kN. LS = ‘long’ screw; SSs = ‘short’ screws.

8.5 Discussion

8.5.1 General Discussion

This study has compared the pullout force of STALIF TT™ cages in normal and OP bone models; the mean cage pullout force was over twice as large in the normal bone model (Figure 8.9 and Figure 8.10) and this result was found to be significant ($p < 0.05$). The results support the findings from Chapters 5-7, where screw fixation was observed to have less strength (measured by pullout force) in the OP bone models, as compared to the normal bone

model. This is in agreement with the literature, which shows that bone mineral density is the strongest predictor of the screw-bone interface and its failure (Cook *et al.*, 2004; Dvorak *et al.*, 2005; Halvorson *et al.*, 1994; Jost *et al.*, 1998; Okuyama *et al.*, 1993; Oxland *et al.*, 1996; Soshi *et al.*, 1991; Wittenberg *et al.*, 1991; Zdeblick *et al.*, 1993).

The test set-up was designed to simulate a “worst case” scenario of STALIF TT™ cage attachment to cancellous ‘bone’. A cancellous bone model (Patel *et al.*, 2008; Chapter 4) was chosen because, *in-vivo*, the majority of the STALIF TT™ screw threads are engaged with cancellous bone within the vertebral body (STALIF TT™ product literature, Surgicraft Ltd., Redditch, UK). However, the aim of this study was not to replicate a possible mode of cage failure *in-vivo* but, instead, to determine the strength of screw fixation for the STALIF TT™ cage. The results of the study are discussed further in the following paragraphs.

Previous designs of the STALIF TT™ cage had used 6.5 mm diameter × 30 mm length cancellous bone screws, which were investigated in Chapters 5 and 7. However, the current design of the STALIF TT™ cage uses the ‘long’ and ‘short’ screws, as defined in this study. Therefore, pullout testing of single ‘long’ and ‘short’ screws was not performed because Chapter 5 has already investigated the individual pullout force of the earlier STALIF TT™ screw design.

It was interesting to find that the mode of cage pullout failure, by pullout of the ‘long’ or two ‘short’ screws, did not significantly affect the cage pullout force; the results suggest that the

mode of cage pullout failure is independent of the type of screw failure. If this is the case, then two screws, or possibly more, may not be better than just one screw for improving the fixation of implants in OP bone. However, this idea is limited by the scope of the pullout criterion used in the current study; there may be cases where two screws can offer a distinct advantage over a single screw, for example, to minimise the risk of torsion of the implant in the spine.

The literature reports that multiple sites of screw fixation can improve screw fixation in OP bone (DeWald and Stanley, 2006; Hu, 1997). In this study, failure of two screws placed in close proximity caused more PU foam fragments than failure of a single, slightly longer, screw in the OP bone model (Figure 8.5). The combination of two ‘short’ screws was also found to show less resistance to cage pullout post-failure, as compared to the ‘long’ screw (Figure 8.7). This may indicate that the failure of multiple screws, in close proximity to each other, causes more damage to bone than a single screw would. Interestingly, the use of two screws to stabilise the STALIF TT™ device is contraindicated (personal communication, Mr A. Fennell, International Sales Director, Surgicraft Ltd., Redditch, UK). Based on the manufacturer’s own tests (Surgicraft Ltd., Redditch, UK), at least three screws are required for optimal biomechanical functioning of the STALIF TT™ device, possibly to reduce torsion, as described in the previous paragraph. The use of two screws upwards and downwards (i.e. a total of four screws) in the STALIF TT™ device may prevent relative rotation at either interface with bone; however, this choice of screw configuration is at the surgeon’s discretion and is beyond the scope of the current study, in which the three-screw configuration was chosen explicitly upon the manufacturer’s recommendation (see §8.3.1).

Whilst the STALIF TT™ screws do not maintain a fixed angle in the STALIF TT™ cage, the pullout forces can be compared to those for the cancellous screw (i.e. a previous design of the STALIF TT™ screw) from Chapter 5. Each screw angle in the STALIF TT™ cage was measured as 48° to the horizontal plane of the cage which, allowing for screw movement in the cage hole, can be approximated to a screw angle of 40° to the vertical axis. Inserted at 40° to the vertical axis, the cancellous screw (from Chapter 5) had the following mean pullout force \pm standard deviation in an OP and normal bone model respectively (see Figure 5.9): 0.32 ± 0.03 N and 0.78 ± 0.10 N. The corresponding values for cage failure by ‘long’ screw pullout (in the present study) were (Figure 8.9 and Figure 8.10): 0.29 ± 0.03 kN ($n = 9$) and 0.68 ± 0.31 kN ($n = 3$). The similarity between these sets of results provides strong evidence that it is the quality of ‘bone’ (modelled by various PU foam densities) that principally influences the strength of screw fixation in bone. Incidentally, in Chapter 5, the mode of pullout failure for screws inserted at angles to the pullout axis (most screws inserted at 10° and at greater angles) involved fracture of the PU block to produce one or more fragments; this was also observed during cage failure by screw pullout in the current study (Figure 8.5 and Figure 8.6).

8.5.2 Calculations for Individual Axial Pullout of the STALIF TT™ Screws

In this study, the screws in a STALIF TT™ cage were at an angle to the axis of pullout; the calculations in this section consider the *axial* screw pullout of STALIF TT™ screws, based on the results from Chapter 5. The predicted shear failure force for axial pullout of the STALIF

TT™ ‘short’ and ‘long’ screws, individually, can be calculated by equation 5.6 (see §5.6.2) using the measurements from Table 8.1; these predictions are shown in Table 8.2. As already mentioned, previous designs of the STALIF TT™ cage had used 6.5 mm diameter \times 30 mm length cancellous bone screws, which were investigated in Chapters 5 and 7. However, the current design of the STALIF TT™ cage uses the ‘long’ and ‘short’ screws, as defined in this study. Therefore, the ratio of the predicted to experimental axial screw pullout force for the cancellous bone screw (see Table 5.3) can be used to estimate the experimental, individual, axial pullout force for the ‘short’ and ‘long’ screws (Table 8.2).

Table 8.2 Calculations for the individual axial pullout force of each type of STALIF TT™ screw: i.e. the ‘short’ (5.5 mm diameter \times 25 mm length) and the ‘long’ (5.5 mm diameter \times 30 mm length) cancellous screws. The predicted shear failure forces are based on equation 5.6. The experimental pullout forces are estimates, using the ratio of predicted versus experimental axial cancellous screw pullout from Chapter 5.

PU foam density (g.cm ⁻³)	Predicted shear failure force (kN)		Estimated experimental axial screw pullout force (kN)	
	‘Short’ screw	‘Long’ screw	‘Short’ screw	‘Long’ screw
0.16	0.16	0.20	0.20	0.24
0.32	0.44	0.53	0.60	0.73

Based on Table 5.3 and Table 8.2, a range of results can be put together to determine the axial pullout force of single STALIF TT™ screws, if tested experimentally. For 0.16 g.cm⁻³ PU foam, an OP bone model, this range is 0.20 – 0.38 kN. For 0.32 g.cm⁻³ PU foam, a normal bone model, the range is 0.60 – 1.15 kN. However, these ranges are only estimates and should not be treated as a complete representation of all types of STALIF TT™ screws.

8.6 Conclusions

- This study has compared the pullout force of STALIF TT™ cages in normal and OP bone models (Patel *et al.*, 2008; Chapter 4); the mean cage pullout force was more than doubled in the normal bone model and this result was found to be significant ($p < 0.05$).
- The mode of STALIF TT™ cage failure, by pullout of either the ‘long’ or the two ‘short’ STALIF TT™ cancellous bone screws, did not significantly affect the cage pullout force.
- The results are consistent with the view that, clinically, there is no benefit in using closely placed multiple screws in OP bone; failure of these screws is likely to cause more bone damage than using a single screw.
- The similarity between the experimental data (for the cancellous bone screw) from Chapter 5 and this chapter provides strong evidence that it is the quality of ‘bone’ (modelled by various PU foam densities) that principally influences the strength of screw fixation in bone.

9. CONCLUSIONS

9.1 Chapter Overview

Throughout this thesis, discussion of the results and specific suggestions for future work has been included in the relevant chapter or section. This last chapter serves to summarise the main conclusions of the thesis by relating them to the original aims outlined in Chapter 1. Each thesis aim is addressed in an individual section (§9.2 to §9.4). Section 9.5 is the final part of the main thesis and presents the concluding remarks.

9.2 Current Practice of Screw Surgery in the Spine

In Chapter 3, a questionnaire study was performed to investigate the current practice of pedicle screw (PS) surgery in the UK and Ireland. PSs are used for posterior instrumentation of the spine, a commonly used procedure to stabilise the spine, which is why this particular form of surgery was investigated. The results showed that the majority of respondent surgeons have experienced problems with PS placement, with several complications arising from the malpositioning of PSs, as discussed in §3.7.1. More than half of the respondent surgeons did not use any spinal navigation systems and they expressed a need for a simple mechanical device to aid PS placement. In particular, potential exists for a simple device to aid PS placement in the cervical and thoracic spine, where PS insertion is more difficult

(because of the complex anatomy). Based on the questionnaire results, surgeons would prefer a pedicle aid that is multiple use, one-piece, hand-held, radiolucent (transparent to X-rays), unilateral (fits on to a single pedicle) and that uses the line of sight principle in traditional open surgery, with no preference as to whether the PS should be loaded into the device before or after entering the body.

The questionnaire also identified a high incidence of problems, especially poor screw purchase, screw loosening and screw pullout, encountered with PS fixation in the osteoporotic (OP) spine, leading to a large number of revision surgery cases. To deal with this, and as discussed in §3.7.3, several studies have reported on the increased pullout resistance of screws augmented with polymethylmethacrylate (PMMA) and various other bone cements in OP bone (Burval *et al.*, 2007; Lotz *et al.*, 1997). However, 22% of questionnaire respondents still faced problems with the cement augmentation of PSs, which may explain why 42% of respondents have had to conduct revision surgery as a result of PS complications in OP bone. Seventy percent of respondents were unfamiliar with screws specifically designed for OP bone; §3.6.12 and §3.7.3 consider the small number of successful screw designs.

The questionnaire, sent to the majority of surgeons known to perform spinal surgery in the UK and Ireland, received a 24% response rate and 16% of the total questionnaires sent out contained useful information. As discussed in §3.7.4, a higher response rate might have resulted in a more representative group of surgeons, but it is in line with other surgical survey studies that have generated responses in the range of 22-49%, (Esses *et al.*, 1993; Glotzbecker *et al.*, 2008; Leece *et al.*, 2006). Thus, it can be concluded that there is a need for a simple

screw positioning device in the spine, as well as a need for an improved screw for OP bone. The work in this thesis did not focus on the design of these products because Surgicraft Ltd. (Redditch, UK), a medical device company that the author collaborated with during this project, did not believe that it was commercially worthwhile for them to develop the above-mentioned products (cf. Biomet UK Ltd. experience in §A.2.7). However, both Surgicraft Ltd. and the author believe that the products would be good subjects for future research; design studies are necessary to address the identified requirements from this questionnaire study.

9.3 Validation of a Test Material to Model OP Bone

Chapter 4 determined the compressive mechanical properties (i.e. Young's modulus, yield strength and energy absorbed to yield) of three commercially available polyurethane (PU) foams and directly compared them with the corresponding values obtained from a study of human OP cancellous bone (Li and Aspden, 1997). The results showed that the Young's modulus and yield strength of (1) closed-cell PU foam of density 0.32 g.cm^{-3} , (2) closed-cell PU foam of density 0.16 g.cm^{-3} and (3) open-cell PU foam of density 0.09 g.cm^{-3} enable them to be used as models for: (1) normal, (2) OP and (3) very low density OP cancellous bone, respectively.

It has not been possible to characterise the PU foams through other forms of testing due to the lack of appropriate data on human bone to compare the results of this study with. For the

advantages mentioned in §2.7, PU foam is a good alternative for the *in-vitro* testing of bone screws, such as in screw pullout testing, when energy dissipation (e.g. in cyclic loading) is not of concern. The foam has been previously used to investigate fixation of bone screws (Battula *et al.*, 2006; Chapman *et al.*, 1996; Gausepohl *et al.*, 2001; Hsu *et al.*, 2005; Inceoglu *et al.*, 2006). However, no previous study has specifically characterised PU foam as an OP cancellous bone model, by comparison of the relevant data with OP bone properties. Therefore, the applications of the PU foams used in this study are relevant in determining factors that affect screw pullout strength, which can aid future design of improved screws for OP bone.

9.4 Factors Affecting Screw Fixation Strength

Chapter 5 investigated the effect of screw insertion angle and thread type on the pullout force of bone screws in various cancellous bone models (PU foams). Screw pullout force decreased as the PU foam density decreased (used to model increasingly OP cancellous bone in this study). In a model of very low density OP bone (0.09 g.cm^{-3} PU foam), screws inserted at 20° , 30° and 40° demonstrated larger pullout forces compared to screws inserted at 0° and 10° angles. For screws inserted at 10° , 20° , 30° and 40° , the resistance to pullout force was observed by compression of the PU foam material above the angled screw; clinically, this suggests that compressed OP bone is stronger than unloaded OP bone (see §5.6.1). In a normal cancellous bone model (0.32 g.cm^{-3} PU foam), screws inserted at 0° and 10° exhibited larger pullout forces compared to screws inserted at 20° , 30° and 40° angles; the results suggest that there is no benefit in placing screws at 40° in normal bone. In the literature, no

previous study has reported any general relationship between bone screw insertion angle and screw pullout force with reference to OP bone.

In Chapter 5, two different screw thread types were investigated; the pullout forces of a cancellous screw were found to be significantly different to those of a cortical screw. As discussed in §5.6 and in the previous literature (Asnis *et al.*, 1996; DeCoster *et al.*, 1990; Gausepohl *et al.*, 2001; Krenn *et al.*, 2008), it can be concluded that the pullout forces of screws are affected by the thread design.

In Chapter 6, a surgeon's idea of "screw" fixation without using a screw thread was explored. This was done by performing pullouts of a dowel, used to model a screw without its threads, in various cancellous bone models (PU foams) to determine the effect of pilot hole diameter on the dowel pullout force. As discussed in §6.6, the results were not found to support the surgeon's idea. Whilst the study was not strictly valid for screw analysis purposes, the results did suggest that pullout force is affected by the size of the pilot hole diameter used prior to screw insertion. This is in agreement with previously published studies on this subject, which have only recently been reported in the literature (Defino *et al.*, 2009; Tsai *et al.*, 2009).

In Chapter 7, screw "togglng" and subsequent axial pullout tests were performed in various cancellous bone models (PU foams) using the same screw types from Chapter 5. Togglng (± 1 mm displacement perpendicular to the axis of screw insertion) of the cortical screw head significantly increased the axial screw pullout force, by more than a factor of two, in an OP

bone model but significantly decreased (9%) the axial screw pullout force in a normal bone model; this supports the idea that compressed OP ‘bone’ (from screw toggling in this case) can improve screw pullout resistance (see §7.6). Toggling (± 1 mm displacement perpendicular to the axis of screw insertion) of the cancellous screw head did not significantly affect the axial screw pullout force in normal and OP bone models; this is likely to be due to the conical core screw design, which locks part of the length of the cancellous screw upon insertion. Overall, the study results imply that a small amount of screw toggling *in-vivo* does not affect its fixation and that any associated bone compression, at the screw-bone interface, may even improve screw fixation in OP bone.

Chapter 8 compared the pullout force of STALIF TT™ spinal fusion cages in normal and OP cancellous bone models (PU foams). Multiple sites of screw fixation can improve screw fixation in OP bone (DeWald and Stanley, 2006; Hu, 1997) and the study results suggest that, clinically, there is no benefit in using closely placed multiple screws in OP bone; based on a screw pullout criterion, failure of these screws is likely to cause more bone damage than using a single screw. The similarity between the experimental data (for the cancellous bone screw) from Chapter 5 and this chapter provides strong evidence that it is the quality of ‘bone’ (modelled by various PU foam densities) that principally influences the strength of screw fixation in bone. This is in agreement with the literature, which shows that bone mineral density is the strongest predictor of the screw-bone interface and its failure (Cook *et al.*, 2004; Dvorak *et al.*, 2005; Halvorson *et al.*, 1994; Jost *et al.*, 1998; Okuyama *et al.*, 1993; Oxland *et al.*, 1996; Soshi *et al.*, 1991; Wittenberg *et al.*, 1991; Zdeblick *et al.*, 1993).

9.5 Concluding Remarks

The strength of a bone screw is particularly important in the early post-operative stages; this is when there is greatest dependency on the hardware to sustain spinal forces, prior to bony fusion. Thus, immediate stability in the OP spine is possible if screws are properly secured to the vertebrae. This thesis has considered PU foam as a synthetic bone model, with compressive mechanical properties comparable to OP and normal human cancellous bone, for the pullout testing of bone screws. Using such a model system removes confounding factors from the experimental design whilst removing the effects of biological variability. However, ultimately, clinical trials are required on living people because bone remodelling will affect the results of screw fixation (Hukins *et al.*, 1999).

It would also be useful to find a transparent, low density bone material, similar to the PU foam used in Chapters 5–8 to see what actually happens during the screw tests; this could provide a better understanding of the mode(s) of screw failure.

Finally, in future, various screw designs should be studied in order to make proper generalisations from this research. However, the deliberate use of the same cortical and cancellous screw types, in Chapters 5 and 7, was made for the purpose of consistency and to analyse the trends for each screw.

In summary, this thesis has provided primary data regarding PS surgery in the UK and Ireland; a questionnaire study directed at spine surgeons has confirmed the potential for a simple screw positioning device and has identified the need for an improved screw for OP bone. To aid in the design of a screw for OP bone, the thesis has considered the idea of a ‘standard’ OP bone model; such a model allows for the investigation of various screw design factors, particularly in screw pullout testing. Direct comparison of the mechanical properties of PU foam, a popular synthetic cancellous bone model, was made with the relevant data for normal and OP human cancellous bone; this has not been previously reported in the literature. Determination of the compressive mechanical properties of 0.32 g.cm^{-3} , 0.16 g.cm^{-3} and 0.09 g.cm^{-3} PU foam enabled them to be used as models for normal, OP and very low density OP, human cancellous bone, respectively. The screw pullout force from these bone models decreased with PU foam density, implying that the quality of bone principally influences the strength of screw fixation. In a unique study, the effect of screw insertion angle on pullout force was investigated in these bone models; the angle of screw insertion and thread design were both found to affect screw pullout force, but not a small amount of screw toggling prior to axial pullout. No benefits in pullout strength were found when placing screws at 40° in a normal bone model or when using closely placed multiple screws in an OP bone model.

APPENDIX A. PRELIMINARY SURVEY (BRITSPINE 2006)

RESULTS

A.1 Introduction

This appendix details the results of the preliminary survey, conducted at the BritSpine 2006 conference (Cardiff, UK), which is mentioned in Chapter 3. In addition to the information gathered from the participating surgeons, conversations between the author and several sales representatives from Surgicraft Ltd. (Redditch, UK), as well as a sales representative from Biomet UK Ltd. (Bridgend, UK), were also held and the information from these discussions was recorded. However, **all statistical results from the preliminary survey only include contributions from the 19 medical professionals.** The reason for this is to maintain consistency within the survey findings; the 19 surgeons interviewed had all undergone a similar surgical training pathway, although not all surgeons were at the same training stage.

§A.2 presents the main questions and answers from the preliminary study; verbal responses have been summarised by bullet points under each sub-heading. §A.3 discusses some final thoughts on the BritSpine 2006 preliminary survey; further discussion can be found in §3.3.4 and §3.3.5.

A.2 Main Questions & Answers

A.2.1 Is there a need for a simple mechanical device to aid pedicle screw (PS) insertion?

Sixty-eight percent of participant surgeons expressed a need for a simple mechanical device to aid PS insertion; 74% of participant surgeons would not use a computed navigation system during surgery (Table A.1).

Table A.1 Percentage response to questions asked to surgeons attending the BritSpine 2006 conference (Cardiff, UK).

Question	Yes (%)	No (%)
Is there a need for a simple mechanical device to aid PS insertion?	68	32
Would you use a computed navigation system during surgery?	26	74

The additional verbal responses provided for the questions in Table A.1 are summarised as follows:

- Some mechanical jigs (devices) already exist so it is not a new concept.
- The idea of a jig is a good one to increase surgical accuracy, provided it is safe and works within the small margin of error associated with spinal operations.

- There is a need for a jig that is cheap and simple (when compared to the computed navigation systems). The PediGuard® (SpineGuard S.A., St Mandé, France), a freehand bipolar drilling tool, is too expensive (the approximate cost of the PediGuard® has been reported as \$2,000 Singapore Dollars (Tan, 2007), which is roughly £1,000). DePuy International Ltd. (Leeds, UK) had a jig (previously AcroMed) that is not sold anymore, but it was clipped on to the transverse process. Open surgery is still used today, so the transverse process can be used for jig attachment. Minimally invasive surgery is currently perceived as fashionable, but it is still in the future.
- A jig may be of use in the thoracic spine, where the pedicles are smaller and the neural canal is narrow. More specifically, the jig could be used in tumour, degenerative and upper thoracic cases. However, one surgeon believes that at least three different jigs would be required just for the thoracic spine.
- A jig can be useful in revision surgery, where sometimes the entire metal-ware is removed due to infection.
- There is possible scope for a jig for use in training, where a jig can increase a surgeon's confidence.
- One surgeon believes that, in spite of the use of PSs for spinal fusion, there will be a levelling off in favour of a trend towards intervertebral disc replacement in the next 5-10 years, but there is a need for a jig to aid deformed spines such as in scoliosis.

- Some surgeons are not “happy” with the situation, but do not think that a jig would work.
- A move towards computational navigation is ideal, so there is no need for a mechanical jig.
- Some surgeons like the tactile feedback from screwing a PS in by hand. They do not believe that a jig will provide the same reassurance.
- Some surgeons are against the idea of the jig and are not interested. They believe a jig is unnecessary and think that the reliance on X-rays for surgical guidance is enough. These surgeons would not use computed navigation systems either. The surgeons believe that even if a jig was just used for training, then there would be a reliance on using the jig, which can lead to inappropriate training.

A.2.2 For those in favour, what kind of pedicle aiming jig would you like?

- It would be useful to have feedback from drill and depth gauges during screw insertion.
- A jig may work if it is patient-specific with a computed tomography (CT) scan.
- The mamillary process can be used as a reference anatomical landmark for the jig.

- It would be good to have a jig that does not require fluoroscopy (a commonly used X-ray procedure that makes it possible to see internal organs in motion).
- A wire on the lamina can be used to locate the pedicle.
- The jig should be designed with multi-functionality in mind. This can include a jig to aid screw insertion, followed by cement injection through the screw etc.
- Surgeons require implant materials that will allow magnetic resonance imaging (MRI) of the spine at a later stage.
- The symmetry of the spine should be considered in the jig design. However, this is not the case for scoliosis, trauma and degenerative spines.
- Anatomy comparison with the hip and knee can be useful – the knee is a good area for a jig.

A.2.3 What problems do you envisage having with a mechanical pedicle aiming device?

- Problems with anatomical landmarks. There is too much inter- and intra-patient variation in anatomy.

- A jig would add time (say an extra hour) to an operation for little benefit. This time factor is also a disadvantage with computed navigation systems.

A.2.4 How big is the problem with PS placement?

- Several surgeons admitted that screws are frequently misplaced, particularly laterally.
- Problems can occur either during screw insertion or removal. It is not known whether these problems are equally weighted between screw insertion and removal.
- Leakage of the cerebrospinal fluid (CSF) can be a problem.
- Infection is a problem.
- Delayed wound healing can be a problem.
- Implant failures is another problem.

A.2.5 Are there any problems with screws in osteoporotic (OP) bone?

- Screw holding power decreases with bone density.

- OP spines are assessed before surgery. A surgeon may put extra screws at the level above and below the normal range to increase holding power. This is a familiar concept in spinal surgery.
- There are problems with revision surgery in OP bone; new bone will grow around the screw making it difficult to remove. Thus, revision surgery for osteoporosis should be avoided.
- One surgeon believes that there is not so much of a problem with OP spines, but instead with tumours and metastases in the vertebral body, in which the screw goes straight through them.
- The use of cement with screws in OP bone is risky. Perforation of the pedicle cortex can cause cement leakage, which allows it to attach to nerve fibres. This can cause neural compression and heat damage to the nerves.

A.2.6 Perspective from the Sales Representatives/Directors from Surgicraft Ltd. (Redditch, UK)

- DePuy International Ltd. (Leeds, UK) and Biomet Inc. (Warsaw, Indiana, USA) are 2 out of approximately 60 companies that have addressed the issue of PSs for OP bone.

- Patents have been filed for a cannulated screw with holes and a distally expandable screw (which have resulted in the corresponding Monarch OP Screw, DePuy Spine Inc., Raynham, Massachusetts, USA and the Omega21™ Expandable Screw, Biomet UK Ltd., Bridgend, Wales).
- Approximately 40% of the spinal technology market is in the USA. The remainder of the market is in Korea, Japan, Australia and few parts of the EU. Korea is a good place to market a pedicle aiming jig, but not a PS for OP bone.
- A new screw design should try to achieve fixation in the pedicle rather than distal fixation in the vertebral body.
- Surgical tools used to insert PSs differ between continents. A mechanical/pneumatic drill is used in the EU, whilst an awl/burr is used in the USA and the screw is then driven in by hand. This is primarily due to heavy legislation on medical devices in the USA.

A.2.7 Perspective from a Sales Representative from Biomet UK Ltd. (Bridgend, UK)

- Biomet UK Ltd. (Bridgend, UK) has applied image guidance systems to the hip and knee. The company tried, but failed, to market a jig for two years on the spine.

- The time factor was one problem. A jig would add set-up time to the operation, in addition to longer anaesthesia times (which some surgeons believe is for little or no benefit).
- The reference anatomy was another problem for the jig's use during initial and revision surgery, particularly where metal-ware had already been laid down in the spine.

A.3 Conclusions

The BritSpine 2006 preliminary survey has provided an input into how a mechanical jig could be devised for PS insertion. However, the advice and information gathered was not as much as expected in helping to generate ideas for the jig design. On the whole, the surgeons interviewed were keen on the idea of a PS jig, but did not offer many suggestions as to how an engineer should go about designing it. It is understood that this was to be expected to some degree; surgeons are medical professionals and not engineers.

APPENDIX B. PEDICLE SCREWS QUESTIONNAIRE

(see next page)



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PEDICLE SCREWS QUESTIONNAIRE

My name is Purvi Patel and I am a PhD student in the Biomedical Engineering Research Group at the University of Birmingham. I am conducting research into methods of pedicle screw placement and the osteoporotic spine. As part of my programme, I have developed the attached questionnaire, the objectives of which are:

- 1) To determine the relevance and importance of a simple device to aid pedicle screw placement.
- 2) To collect opinions and experiences on pedicle screw surgery to aid in its design.
- 3) To determine the criteria for the design of such a device.

I would be grateful if you could take a few minutes to complete it. The findings will be used in an academic doctoral research project in conjunction with a medical device company.

All responses will be treated with the utmost confidence and the survey results will only be presented in aggregated format.

If you have any questions regarding the survey, I can be contacted at:

Purvi Patel
Bio-medical Engineering Research Centre
Mechanical & Manufacturing Engineering
School of Engineering
University of Birmingham
Edgbaston
Birmingham
B15 2TT

Tel: [REDACTED]

Email: [REDACTED]

Please return the completed form in the business reply envelope (enclosed) by **Friday 13th April 2007.**

Thank you for taking part in this survey.

Are you: (a) a neuro-surgeon? ☐ or (b) an orthopaedic surgeon? ☐

Please tick the appropriate box.

Please specify your current position below (e.g. Specialist Registrar or Consultant etc.):

This questionnaire is double-sided and consists of 11 questions.

Please answer all questions.

You are encouraged to discuss your responses with colleagues, such that your responses do not have to be based on your specific surgical experience.

For choice questions, please tick the relevant boxes.

For questions that require you to write an answer, please print your responses in block letters.

Please turn over the page.

1. Do you think there is a need for a simple device to aid pedicle screw placement?

Please tick the appropriate box.

YES

☐

NO

☐

Please give reasons for your answer in the box below:

2. What spinal systems do you currently use to aid pedicle screw placement?

Please tick as many as appropriate.

a) None

☐

b) PediGuard™ (SpineVision®)

☐

c) SpineAssist (MAZOR Surgical Technologies)

☐

d) CD HORIZON SPIRE™ Spinal System (Medtronic Sofamor Danek)

☐

e) Other(s) (please specify) _____



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3. What are the good features and limitations/shortfalls of these particular spinal systems that you use?

Please write your comments in the relevant boxes below.

a) Reasons for using the PediGuard™ (SpineVision®):

GOOD FEATURES	LIMITATIONS & SHORTFALLS

b) Reasons for using the SpineAssist (MAZOR Surgical Technologies):

GOOD FEATURES	LIMITATIONS & SHORTFALLS

c) Reasons for using the CD HORIZON SPIRE™ Spinal System (Medtronic Sofamor Danek):

GOOD FEATURES	LIMITATIONS & SHORTFALLS

d) Reasons for using any other spinal systems you have specified in Question 2(e):

GOOD FEATURES	LIMITATIONS & SHORTFALLS



4. What is your idea of the 'perfect' pedicle screw path/entry point/trajectory for the positioning of a pedicle screw?

Please write your comments in the box below. In addition, you may sketch your ideal system for pedicle screw placement in the box below.

5. In which regions of the human spine have you inserted pedicle screws?

Please tick as many as appropriate.

Cervical

11

Lumbar

10

Thoracic

11

Sacral

6. Have you experienced any problems with pedicle screw placement in patients?

Please tick the appropriate box.

YES

11

NO

11

If yes, please specify the problems in the box below:

Case No.	Case Name	Case Address	Case City	Case State	Case Zip	Case Phone	Case Email	Case Date	Case Status	Case Notes
1	John Doe	123 Main St	New York	NY	10001	212-555-1234	john.doe@example.com	2023-10-27	Open	Initial contact made. Client is interested in our services.
2	Jane Smith	456 Elm St	Los Angeles	CA	90001	310-555-5678	jane.smith@example.com	2023-10-28	Closed	Client has decided to go with a competitor.
3	Bob Johnson	789 Oak St	Chicago	IL	60601	312-555-9012	bob.johnson@example.com	2023-10-29	In Progress	Working on proposal for client. Meeting scheduled for next week.
4	Alice Brown	101 Pine St	San Francisco	CA	94101	415-555-3456	alice.brown@example.com	2023-10-30	Open	Client has requested a demo of our software.
5	Charlie Davis	202 Maple St	Houston	TX	77001	281-555-7890	charlie.davis@example.com	2023-10-31	Closed	Client has signed the contract. Project start date is next month.
6	Diana Evans	303 Cedar St	Phoenix	AZ	85001	602-555-2345	diana.evans@example.com	2023-11-01	In Progress	Client is reviewing our proposal. Follow-up call scheduled.
7	Frank Green	404 Birch St	Philadelphia	PA	19101	215-555-6789	frank.green@example.com	2023-11-02	Open	Client has expressed interest in our services. Further discussion needed.
8	Grace Hill	505 Walnut St	San Diego	CA	92101	619-555-0123	grace.hill@example.com	2023-11-03	Closed	Client has decided to proceed with our services. Contract signed.
9	Henry King	606 Elm St	Portland	OR	97201	503-555-4567	henry.king@example.com	2023-11-04	In Progress	Client is in the process of reviewing our proposal. Meeting set for Friday.
10	Ivy Lee	707 Oak St	Seattle	WA	98101	206-555-8901	ivy.lee@example.com	2023-11-05	Open	Client has requested more information about our services.
11	Jack Miller	808 Pine St	Denver	CO	80201	303-555-2345	jack.miller@example.com	2023-11-06	Closed	Client has signed the contract. Project start date is next week.
12	Karen Wilson	909 Cedar St	San Jose	CA	95101	408-555-6789	karen.wilson@example.com	2023-11-07	In Progress	Client is reviewing our proposal. Follow-up call scheduled.
13	Leo White	1010 Birch St	San Antonio	TX	78201	214-555-0123	leo.white@example.com	2023-11-08	Open	Client has expressed interest in our services. Further discussion needed.
14	Mia Black	1111 Walnut St	San Diego	CA	92101	619-555-4567	mia.black@example.com	2023-11-09	Closed	Client has decided to proceed with our services. Contract signed.
15	Noah Gray	1212 Elm St	Portland	OR	97201	503-555-8901	noah.gray@example.com	2023-11-10	In Progress	Client is in the process of reviewing our proposal. Meeting set for Friday.
16	Olivia Brown	1313 Oak St	Seattle	WA	98101	206-555-2345	olivia.brown@example.com	2023-11-11	Open	Client has requested more information about our services.
17	Peter Green	1414 Pine St	Denver	CO	80201	303-555-6789	peter.green@example.com	2023-11-12	Closed	Client has signed the contract. Project start date is next week.
18	Quinn White	1515 Cedar St	San Jose	CA	95101	408-555-0123	quinn.white@example.com	2023-11-13	In Progress	Client is reviewing our proposal. Follow-up call scheduled.
19	Rachel Black	1616 Birch St	San Antonio	TX	78201	214-555-4567	rachel.black@example.com	2023-11-14	Open	Client has expressed interest in our services. Further discussion needed.
20	Samuel Gray	1717 Walnut St	San Diego	CA	92101	619-555-8901	samuel.gray@example.com	2023-11-15	Closed	Client has decided to proceed with our services. Contract signed.
21	Tina Brown	1818 Elm St	Portland	OR	97201	503-555-2345	tina.brown@example.com	2023-11-16	In Progress	Client is in the process of reviewing our proposal. Meeting set for Friday.
22	Uma White	1919 Oak St	Seattle	WA	98101	206-555-6789	uma.white@example.com	2023-11-17	Open	Client has requested more information about our services.
23	Victor Black	2020 Pine St	Denver	CO	80201	303-555-0123	victor.black@example.com	2023-11-18	Closed	Client has signed the contract. Project start date is next week.
24	Wendy Gray	2121 Cedar St	San Jose	CA	95101	408-555-4567	wendy.gray@example.com	2023-11-19	In Progress	Client is reviewing our proposal. Follow-up call scheduled.
25	Xavier Brown	2222 Birch St	San Antonio	TX	78201	214-555-8901	xavier.brown@example.com	2023-11-20	Open	Client has expressed interest in our services. Further discussion needed.
26	Yara White	2323 Walnut St	San Diego	CA	92101	619-555-2345	yara.white@example.com	2023-11-21	Closed	Client has decided to proceed with our services. Contract signed.
27	Zoe Black	2424 Elm St	Portland	OR	97201	503-555-6789	zoe.black@example.com	2023-11-22	In Progress	Client is in the process of reviewing our proposal. Meeting set for Friday.
28	Adam Gray	2525 Oak St	Seattle	WA	98101	206-555-0123	adam.gray@example.com	2023-11-23	Open	Client has requested more information about our services.
29	Bella White	2626 Pine St	Denver	CO	80201	303-555-4567	bella.white@example.com	2023-11-24	Closed	Client has signed the contract. Project start date is next week.
30	Caleb Black	2727 Cedar St	San Jose	CA	95101	408-555-8901	caleb.black@example.com	2023-11-25	In Progress	Client is reviewing our proposal. Follow-up call scheduled.
31	Diana Brown	2828 Birch St	San Antonio	TX	78201	214-555-2345	diana.brown@example.com	2023-11-26	Open	Client has expressed interest in our services. Further discussion needed.
32	Ethan White	2929 Walnut St	San Diego	CA	92101	619-555-6789	ethan.white@example.com	2023-11-27	Closed	Client has decided to proceed with our services. Contract signed.
33	Fiona Black	3030 Elm St	Portland	OR	97201	503-555-0123	fiona.black@example.com	2023-11-28	In Progress	Client is in the process of reviewing our proposal. Meeting set for Friday.
34	Gavin Gray	3131 Oak St	Seattle	WA	98101	206-555-4567	gavin.gray@example.com	2023-11-29	Open	Client has requested more information about our services.
35	Hannah White	3232 Pine St	Denver	CO	80201	303-555-8901	hannah.white@example.com			

7. (a) In your opinion, which regions of the human spine would benefit from a simple device to aid pedicle screw placement?

Please tick as many as appropriate.

Cervical	<input type="checkbox"/>	Lumbar	<input type="checkbox"/>
Thoracic	<input type="checkbox"/>	Sacral	<input type="checkbox"/>

(b) Why do you think this? *Please write your comments in the relevant boxes below.*

Cervical Region – reasons for a simple device to aid pedicle screw placement:

Thoracic Region – reasons for a simple device to aid pedicle screw placement:

Lumbar Region – reasons for a simple device to aid pedicle screw placement:

Sacral Region – reasons for a simple device to aid pedicle screw placement:

Pedicle Screw Device Design Questions*Please tick the appropriate boxes.***8. Would you prefer a simple device for pedicle screw placement that is:**

- | | | | | | |
|----|---|--------------------------|----|---|--------------------------|
| a) | Free-hand (i.e. resting) | <input type="checkbox"/> | or | Hand-held | <input type="checkbox"/> |
| b) | Radiolucent | <input type="checkbox"/> | or | Radiopaque | <input type="checkbox"/> |
| c) | Single-use (i.e. disposable) | <input type="checkbox"/> | or | Multiple-use | <input type="checkbox"/> |
| d) | One piece | <input type="checkbox"/> | or | Modular | <input type="checkbox"/> |
| e) | Unilateral | <input type="checkbox"/> | or | Bilateral | <input type="checkbox"/> |
| f) | Uses computed navigation | <input type="checkbox"/> | or | Line of sight | <input type="checkbox"/> |
| g) | Uses minimally invasive surgical techniques | <input type="checkbox"/> | or | Traditional open surgery | <input type="checkbox"/> |
| h) | Has the screw loaded to the device prior to entering the body | <input type="checkbox"/> | or | Screw loaded to the device once it is in the body | <input type="checkbox"/> |

Osteoporosis in the Spine

9. What problems, if any, have you experienced with pedicle screws in treating patients with an osteoporotic spine?

Please tick as many as appropriate.

a) Poor screw fixation/purchase ☐

b) Screw loosening ☐

c) Screw pull-out *during* surgery ☐

d) Screw pull-out *after* surgery ☐

e) Problems with cement augmentation of pedicle screws ☐

f) Loss of correction of the spine ☐

g) Prominent/protruding hardware on the spine ☐

h) Screw cut-up of osteoporotic vertebrae
(particularly at the vertebral end-plates) ☐

i) Requirement of revision surgery ☐

j) Other problem(s) *(please specify)* _____

10. Historically, do you know of any screws that have been designed for osteoporotic bone?

Please tick the appropriate box.

YES

☐

NO

☐

If yes, were these screws successful or unsuccessful in osteoporotic bone?

Please write your comments in the box below.

11. Do you have any other suggestions or opinions about pedicle screws, systems to assist spinal surgery, the design of a pedicle screw placement device or osteoporosis in the spine?

Please write your comments in the box below.

Thank you for taking the time to complete this questionnaire.

Your responses will be treated with the utmost confidence and the survey results will only be presented in aggregated format.

End of Questionnaire - Please return the completed form to the address on page 1.



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APPENDIX C. CHI-SQUARED TEST ANALYSIS

The Chi-squared test for association can be analysed using a contingency table; Table C.1 is the contingency table, generated using MINITAB® Release 15 Statistical Software (Minitab Inc., Pennsylvania, USA), for the response to Question 6 by surgeon speciality for the Pedicle Screws (PSs) Questionnaire (see Chapter 3). The null hypothesis is that there is no association between Question 6 response and surgeon speciality; the alternative hypothesis is that there is an association of any kind. Table C.1 shows the observed and expected frequencies if the null hypothesis were true. The row and column totals, i.e. the marginal totals, of the observed frequencies have been used to find the expected frequencies for tables with these totals, such that the expected frequency was found (Bland, 2000) by:

$$\frac{\text{row total} \times \text{column total}}{\text{grand total}} \quad (\text{C.1})$$

Table C.1 Observed and expected frequencies of categories of question response as compared with surgeon speciality for Question 6 of the Pedicle Screws Questionnaire (see Chapter 3).

Question 6 Response	Orthopaedic Surgeon		Neurosurgeon		Total
	Observed	Expected	Observed	Expected	
Yes	42	40.26	10	11.74	52
No	6	7.74	4	2.26	10
Total	48	48	14	14	62

These observed and expected frequencies were then compared and measured, using MINITAB®, by the Chi-squared test statistic (Bland, 2000):

$$\sum_{\text{all cells}} \frac{(\text{observed frequency} - \text{expected frequency})^2}{\text{expected frequency}} \quad (\text{C.2})$$

By convention, the Chi-squared test is valid provided “at least 80% of the expected frequencies exceed 5 and all the expected frequencies exceed 1” (Bland, 2000; Cochran, 1977). Given that the criterion for Chi-squared testing was not always met and could, therefore, lead to suspect results, two other statistical methods (Bland, 2000) were employed to verify the statistical findings; these were the application of Yates’ continuity correction (calculated by hand) and Fisher’s exact test (using MINITAB®). The significance level was set at 0.05 for all tests.

A Chi-squared test found no significant difference ($p = 0.150$) between the neurosurgeons and orthopaedic surgeons and their response to Question 6. However, one of the expected frequencies’ (which comprised 25% of the total expected frequencies) did not exceed 5 (the value was 2.26 – see Table C.1), which meant the statistical test was not strictly valid. To improve the approximation to the Chi-squared distribution, Yates’ continuity correction (Bland, 2000) was applied to the data for Question 6; the results led to the same conclusion: no association was found ($p > 0.05$) between surgeon speciality and whether or not a surgeon has experienced problems with PS placement. As a double check, Fisher’s exact test (Bland, 2000) was also applied to the data; this method, based on a discrete distribution of the data, also led to the same finding of no association ($p = 0.213$) between surgeon speciality and Question 6 response.

APPENDIX D. EULER BUCKLING CALCULATIONS

This appendix relates to §4.5, with regard to the critical load required for Euler buckling to occur during compression of the cylindrical polyurethane (PU) foam samples. An in-depth description of Euler buckling and the formulae used in this appendix can be found in Gere and Timoshenko (1997).

In order to closely match the compression testing conditions described in Chapter 4, consider a column that is free to shorten under an axial load; vertical movement can occur but rotation and horizontal displacement are prevented. When this column buckles in the first mode of Euler buckling (described by the integer $n = 1$), the shape of the column is as shown in Figure D.1.



Figure D.1 First mode buckling shape ($n = 1$) of a vertical column under an axial load (an Euler column); the column is fixed against rotation and horizontal displacement at both ends.

The critical axial load, P_{cr} , for Euler buckling of this column (Figure D.1) with fixed ends (Gere and Timoshenko, 1997) is:

$$P_{cr} = \frac{4\pi^2 EI}{L^2} \quad (\text{D.1})$$

where L is the height of the column; EI is the bending stiffness of the column, which is the product of the Young's modulus, E , of its material and the second moment, I , of its cross-sectional area about the neutral axis. For the circular area of a column's cross-section, I is given (Gere and Timoshenko, 1997) by:

$$I = \frac{\pi r^4}{4} \quad (\text{D.2})$$

where r is the radius of the column's cross-sectional area.

Equations D.1 and D.2 can be used to calculate the maximum allowable axial load (i.e. the critical load) that the PU foam cylinders can support, such that they do not buckle in the shape of the first mode of Euler buckling (Figure D.1). Table D.1 shows the calculated critical loads required to cause buckling of the six different types of PU foam cylinders (9 mm diameter), used in Chapter 4's study.

Table D.1 Critical loads for buckling of the PU foam cylinders (9 mm diameter) used in the compression study (Chapter 4). The critical loads were calculated using equations D.1 and D.2, where the mean values for E , from Chapter 4, have been used.

Density of PU Foam Cylinder (g.cm^{-3})	Cylinder height, L (mm)	Mean Young's Modulus, E (MPa)	Critical Load, P_{cr} (kN)
0.09	3.9	0.3	0.3
0.09	7.7	0.7	0.2
0.16	3.9	19	15.9
0.16	7.7	41	8.8
0.32	3.9	66	55.2
0.32	7.7	145	31.1

In the compression study, the approximate maximum loads experienced by the 0.09 g.cm^{-3} , 0.16 g.cm^{-3} and 0.32 g.cm^{-3} PU cylinders were, respectively: 0.006 kN, 0.14 kN and 0.49 kN. All PU test cylinders experienced loads less than the critical load required for Euler buckling (Table D.1).

APPENDIX E. EXAMPLES OF THE VARIABLE PATTERN GENERATED BY THE SCREW PULLOUT TEST RESULTS

In Chapter 5, the same cortical and cancellous screws were used for the axial and angled screw pullouts. Repeating the pullout tests, using the same cortical and cancellous screws, has the advantage of providing an average result for that particular screw. In order to check for a variable pattern of results, the maximum load recorded (defined as the screw pullout strength in Chapter 5) was plotted against the test number for a small selection of the data sets (Figures E.1, E.2 and E.3).

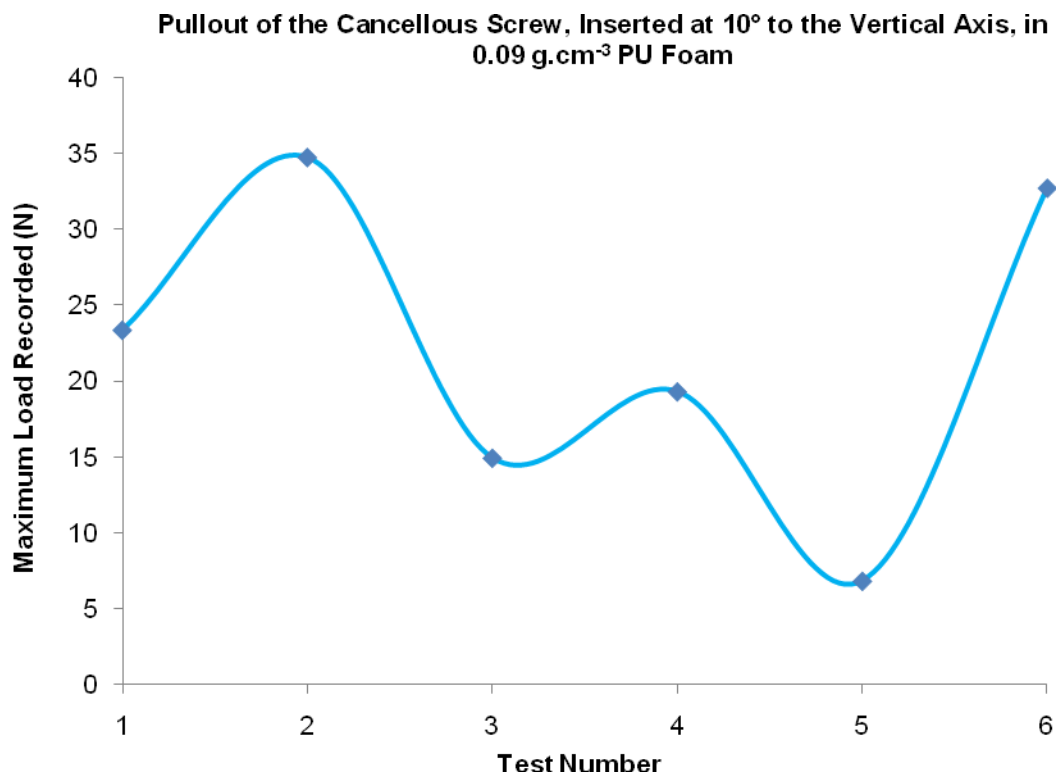


Figure E.1 Variable pattern of screw pullout test results for a data set using 0.09 g.cm⁻³ PU foam.

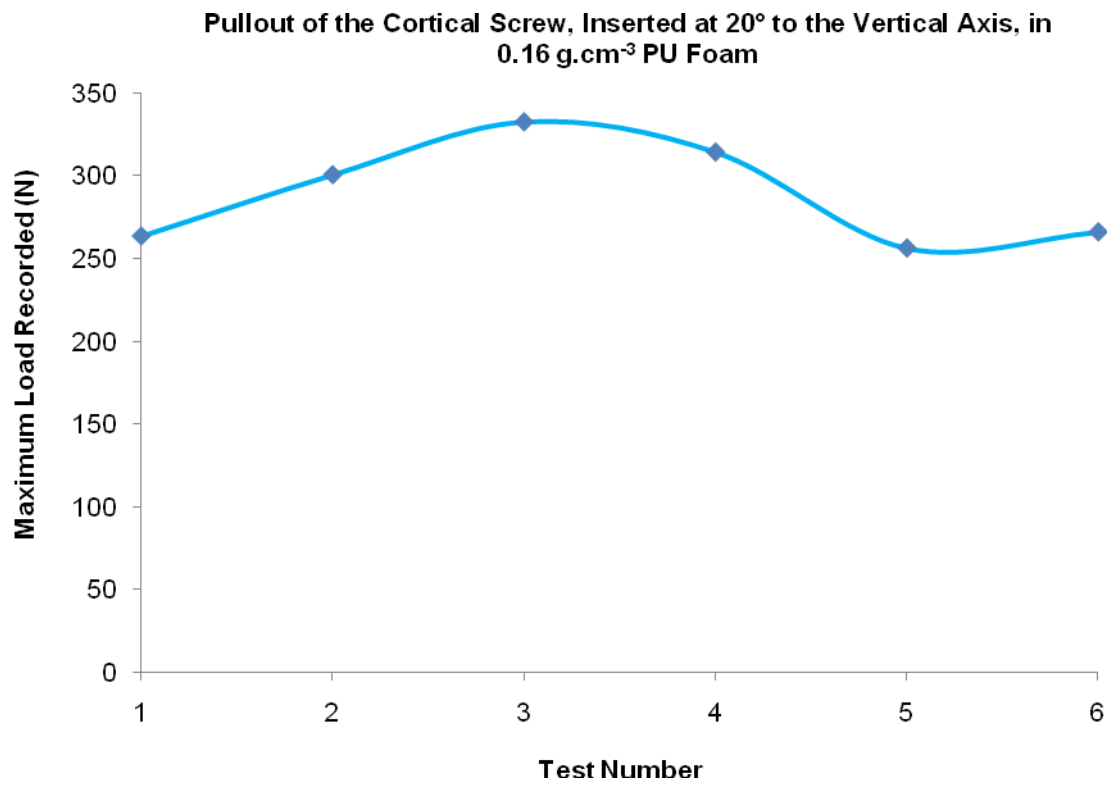


Figure E.2 Variable pattern of screw pullout test results for a data set using 0.16 g.cm⁻³ PU foam.

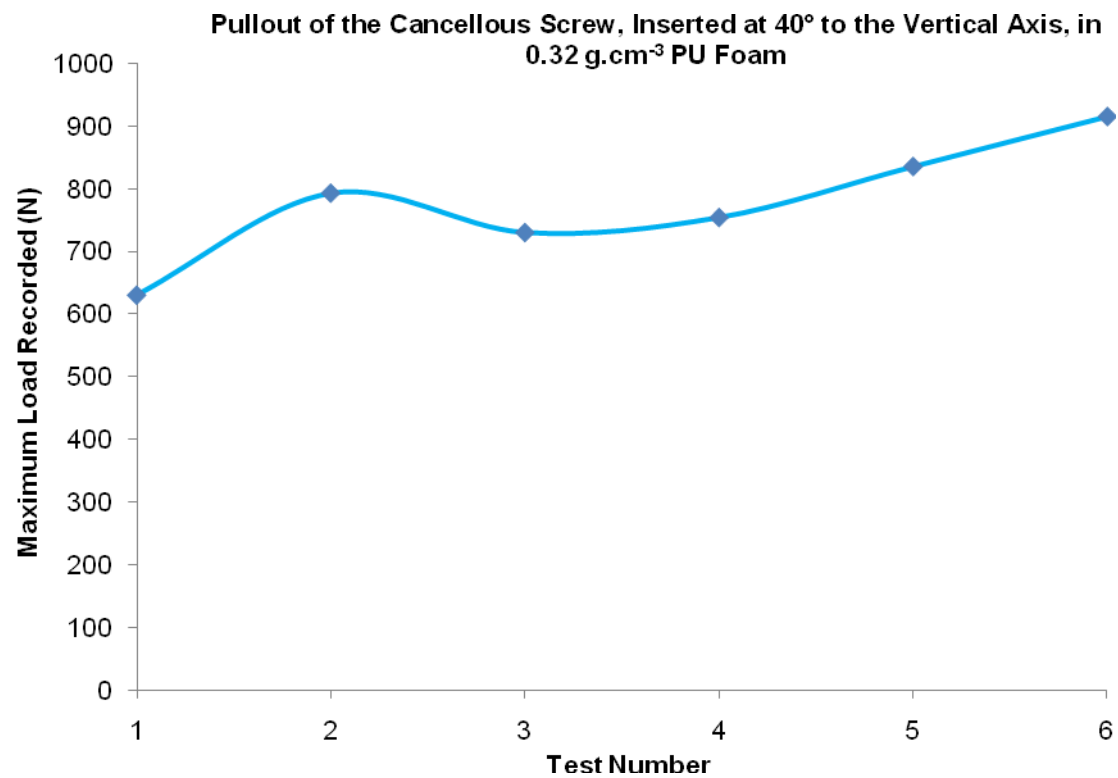


Figure E.3 Variable pattern of screw pullout test results for a data set using 0.32 g.cm⁻³ PU foam.

Figures E.1, E.2 and E.3 each show no clear trend between the maximum load recorded and the pullout test number; all of the graphs show a variable pattern of test results, suggesting that the pullout tests were not affected by screw re-use.

APPENDIX F. PEIRCE'S CRITERION FOR THE ELIMINATION OF OUTLIERS FROM EXPERIMENTAL DATA

In Chapters 5-8, several data sets contained one or two data points that were considerably outside the range of the others obtained; such outliers can influence the mean and standard deviation (SD) of the measurements. Therefore, Peirce's criterion was used to test for and exclude statistical outliers from the experimental data. This appendix briefly describes the method from Peirce's criterion; further information can be found in Hawkins (1980), Peirce (1852) and Ross (2003).

Peirce's criterion is based on the model that a mixture of distributions, with unknown probability, generated each data set under consideration. The criterion is a rigorous method, based on probability theory, that is readily applied in the case of several suspicious data points using the table in Ross (2003); the principle method is summarised below:

1. The mean and SD is calculated for the sample data set.
2. The ratio (R) of the maximum acceptable deviation (of a data point from the data mean) to the SD is obtained from Peirce's table (Ross, 2003), depending on the size of the data set and assuming one suspicious data point to begin with.
3. The maximum acceptable deviation is calculated by multiplying the SD by R .
4. The actual deviations for the suspicious data points are calculated by taking the difference (as a modulus value) between the suspicious data point and the mean. This is repeated for every suspicious data point in the data set.

5. The suspicious data point is eliminated if the actual deviation is greater than the maximum acceptable deviation. The suspicious data point is retained if the actual deviation is less than the maximum acceptable deviation.
6. If one data point is eliminated, the process above is repeated assuming two suspicious data points now, which affects the value of R obtained from Peirce's table (Ross, 2003). Steps 2-5 are repeated, using the original mean and SD, followed by Step 8.
7. If more than one data point is eliminated in the above test, assume the next highest value of suspicious data points, which affects the value of R obtained from Peirce's table (Ross, 2003). For example, if two data points are eliminated in Step 5, assume the case of three suspicious data points, using the original mean and SD.
8. Steps 2-5 are repeated, sequentially increasing the number of suspicious data points, until no more data points need to be eliminated.
9. The new value of the mean and SD is calculated for the reduced data set.

A detailed example of how to apply Peirce's criterion to a set of data points is provided by Ross (2003); this was consulted before applying the criterion to the data sets in Chapters 5-8.

APPENDIX G. MEASURING THE SCREW ANGLE IN THE STALIF TT™ CAGE

This appendix relates to §8.3.1, with regard to the screw angle in the STALIF TT™ cage; the angle was measured as 48° to the horizontal (i.e. transverse) plane of the cage. Measurement of this screw angle involved the manufacture of a dowel (by Mr A. Saywell, Surface & Coordinate Metrology Laboratory, School of Mechanical Engineering, University of Birmingham, UK) that was able to fit tightly into the screw hole of the STALIF TT™ cage; the STALIF TT™ screws themselves were unable to be used because they move within the screw holes and would, therefore, provide inaccurate angular measurements. The dimensions of the custom-made dowel were measured with digital vernier callipers (Fisher Scientific UK Ltd., Loughborough, Leicestershire, UK) as: length = 25 mm; core diameter = 5.65 mm; dowel cap-head width = 7.88 mm.

This was followed by measurement of the dowel angle in the STALIF TT™ cage using a set-up involving a sine table with slip gauges, a height gauge and a dial test indicator (all available from the Surface & Coordinate Metrology Laboratory, mentioned above, and supplied by Bowers Metrology UK, Bordon, Hampshire, UK). Figure G.1 illustrates the test set-up. Mr R. Beck (in the Surface & Coordinate Metrology Laboratory) manufactured the custom 4° aluminium taper block to correctly align the STALIF TT™ cage (which has a corresponding 4° taper angle on its top and bottom surface) for the set-up. A series of slip gauges were used to angle the sine table, which subsequently ensured horizontal alignment of

the dowel in the STALIF TT™ cage. The slip gauges measured up to 7.550 inches under the sine table; however, the actual height under the sine table was 7.450 inches because of a 0.1 inch gap between the roller and the sine table (Figure G.1). In a sine table book, provided by the Surface & Coordinate Metrology Laboratory, a 7.450 slip gauge measurement corresponded to a 48° angle measurement of the dowel relative to the horizontal plane of the STALIF TT™ cage.

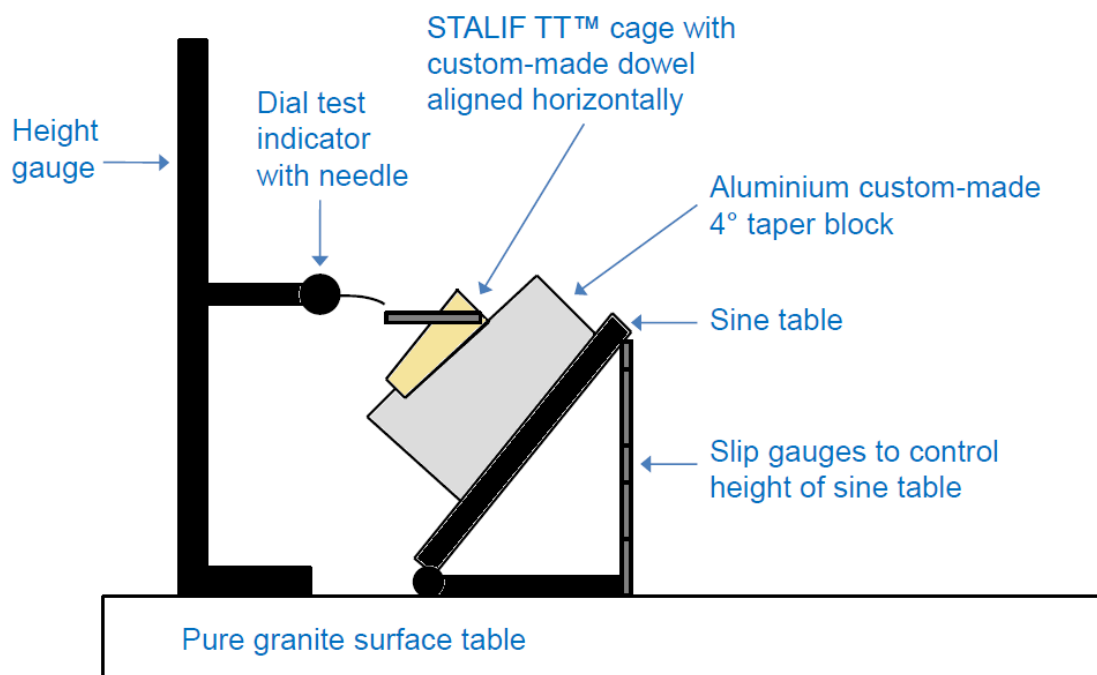


Figure G.1 Test set-up to determine the screw angle (modelled using a custom-made dowel with a tight-fit) in the STALIF TT™ cage.

APPENDIX H. ACCURACY OF THE ELF3200 AND ELF3300 MATERIALS TESTING MACHINES

In Chapter 4, compression tests were conducted using an ELF3200 (for 0.09 g.cm^{-3} polyurethane (PU) foam) or an ELF3300 (for 0.16 and 0.32 g.cm^{-3} PU foams) materials testing machine (Bose Corporation, ElectroForce Systems Group, Minnetonka, MN, USA). The ELF3200 testing machine is fitted with a load cell of full scale 225 N (maximum error 0.21% of the full scale) and a displacement transducer with full scale 13 mm (maximum error 0.49% of the full scale). The ELF3300 testing machine is fitted with a load cell of full scale 5100 N (maximum error 0.1% of the full scale) and a displacement transducer with full scale 25 mm (maximum error 0.28% of the full scale).

In Chapter 5, screw pullout tests were performed using the ELF3300 materials testing machine; the maximum load recorded was 1624 N , for pullout of the cancellous screw, inserted at 10° , from 0.32 g.cm^{-3} PU foam. Based on the maximum load recorded and dimensions given by the manufacturer, the mechanical stability of the machine test frame was calculated (Gere and Timoshenko, 1997) as follows: maximum deflection at the centre of the cross-head = $6.4 \times 10^{-6} \text{ mm}$; maximum deflection at the centre of the columns = $3.6 \times 10^{-5} \text{ mm}$. This systematic error was considered negligible when compared to the screw displacement up to the maximum pullout force (approximately $2 - 3 \text{ mm}$).

In Chapter 6, dowel pullout tests were performed using the ELF3300 materials testing machine. During pullout, the loads experienced by the dowel were considerably lower than those experienced by the cortical and cancellous screws in Chapter 5's pullout study; thus the systematic errors for the ELF3300 testing machine were considered to be negligible for the dowel study in Chapter 6 as well.

In Chapter 7, screw toggling and subsequent axial pullout tests were performed with the ELF 3300 materials testing machine; the axial screw pullout force always exceeded the initial screw toggling force. The maximum load recorded during these tests was 1426 N, for axial pullout after cancellous screw toggling in 0.32 g.cm^{-3} PU foam. Based on the maximum load recorded and the dimensions given by the manufacturer, the mechanical stability of the machine test frame was calculated (Gere and Timoshenko, 1997) as follows: maximum deflection at the centre of the cross-head = 5.6×10^{-6} mm; maximum deflection at the centre of the columns = 3.1×10^{-5} mm. This systematic error was considered negligible when compared to the screw displacement up to the maximum pullout force (approximate range 1.5 – 3.0 mm).

In Chapter 8, STALIF TT™ cage pullouts were performed using the ELF3300 materials testing machine; the maximum load recorded was 1032 N. Based on the maximum load recorded and the dimensions given by the manufacturer, the mechanical stability of the machine test frame was calculated (Gere and Timoshenko, 1997) as follows: maximum deflection at the centre of the cross-head = 4.1×10^{-6} mm; maximum deflection at the centre of the columns = 2.3×10^{-5} mm. This systematic error was considered negligible when compared

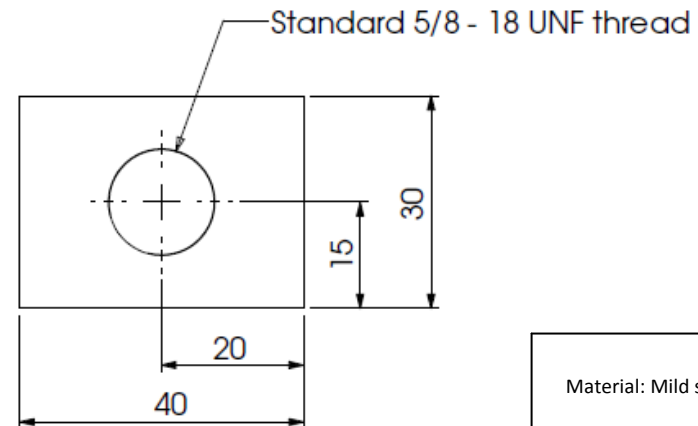
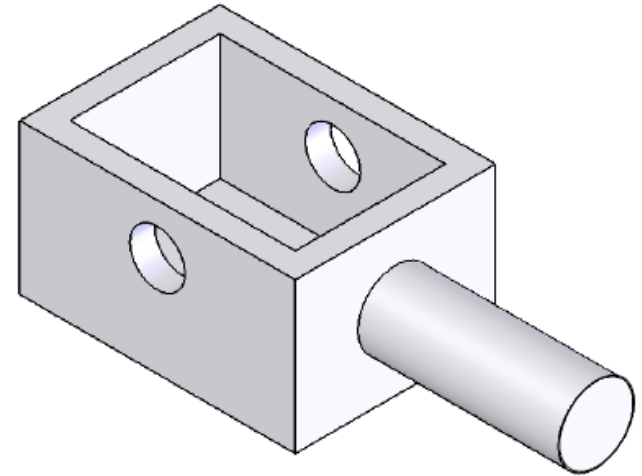
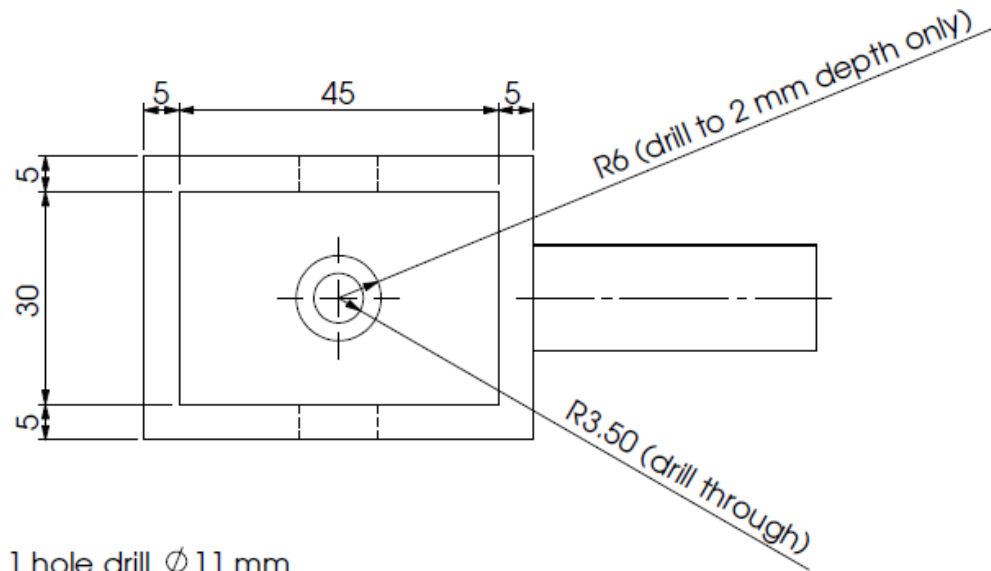
to the STALIF TT™ screw(s) displacement up to the maximum pullout force (approximately 4 - 8 mm).

The load cells for the ELF3200 and ELF3300 testing machines are calibrated annually to the United Kingdom Accreditation Service (UKAS) standard. Prior to using the ELF 3300 materials testing machine for all the mechanical testing outlined in this thesis, the load cell calibration was double checked by placing machine weights (one 0.5 kg and one 1kg machine weight) on the machine to test for an agreement in the load measurement; this was repeated six times, resulting in a successful agreement between the load cell measurements and the machine weights loads.

APPENDIX J. CAD DRAWINGS OF TEST RIGS

This appendix contains engineering CAD drawings for the following test rigs:

- Axial (0°) pullout fixture (combined as a screw toggling fixture)
- Top part of axial pullout fixture
- Locking pin for axial pullout fixture
- Angled screw pullout fixture
- Bottom part of pullout fixture
- Sides of bottom part of pullout fixture
- Dowel design
- Flat plate to insert dowel
- L-shaped plate (for screw toggling)
- Bone block chamber (for screw toggling)
- Upper plate of screw toggling chamber
- Right-hand side plate of screw toggling chamber
- Extension thread adapter for screw toggling fixture



Material: Mild steel

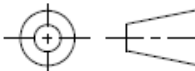
Mechanical Engineering
University of Birmingham

All dimensions in mm

Tolerance unless otherwise stated:
whole numbers ± 0.25
one decimal place ± 0.10
two decimal places ± 0.05

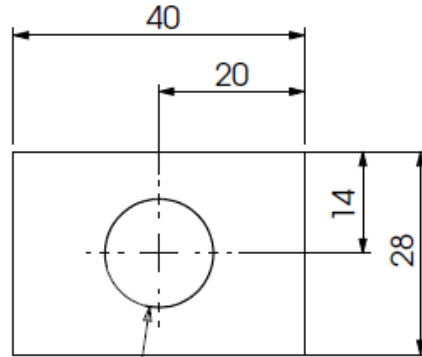
SCALE 1:1

Third angle
projection

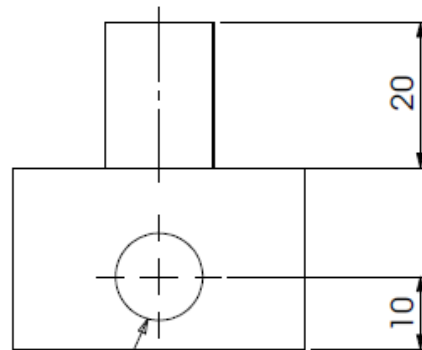
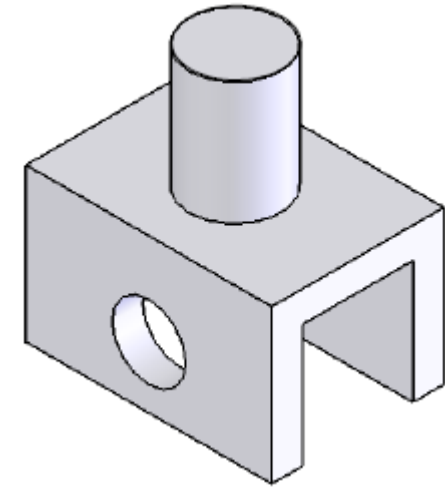


Drawn by Purvi Patel

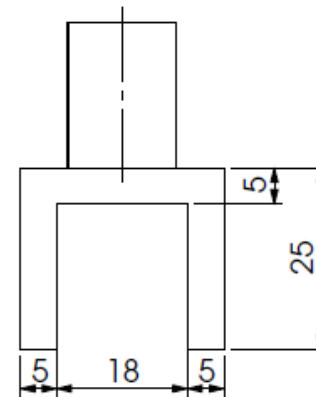
Axial (0 degrees) pullout fixture &
Screw toggling fixture



Standard 5/8 - 18 UNF
thread



1 hole drill \varnothing 12 mm
through



Material: Stainless steel

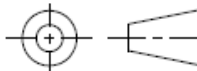
Mechanical Engineering
University of Birmingham

All dimensions in mm

Tolerance unless otherwise stated:
whole numbers ± 0.25
one decimal place ± 0.10
two decimal places ± 0.05

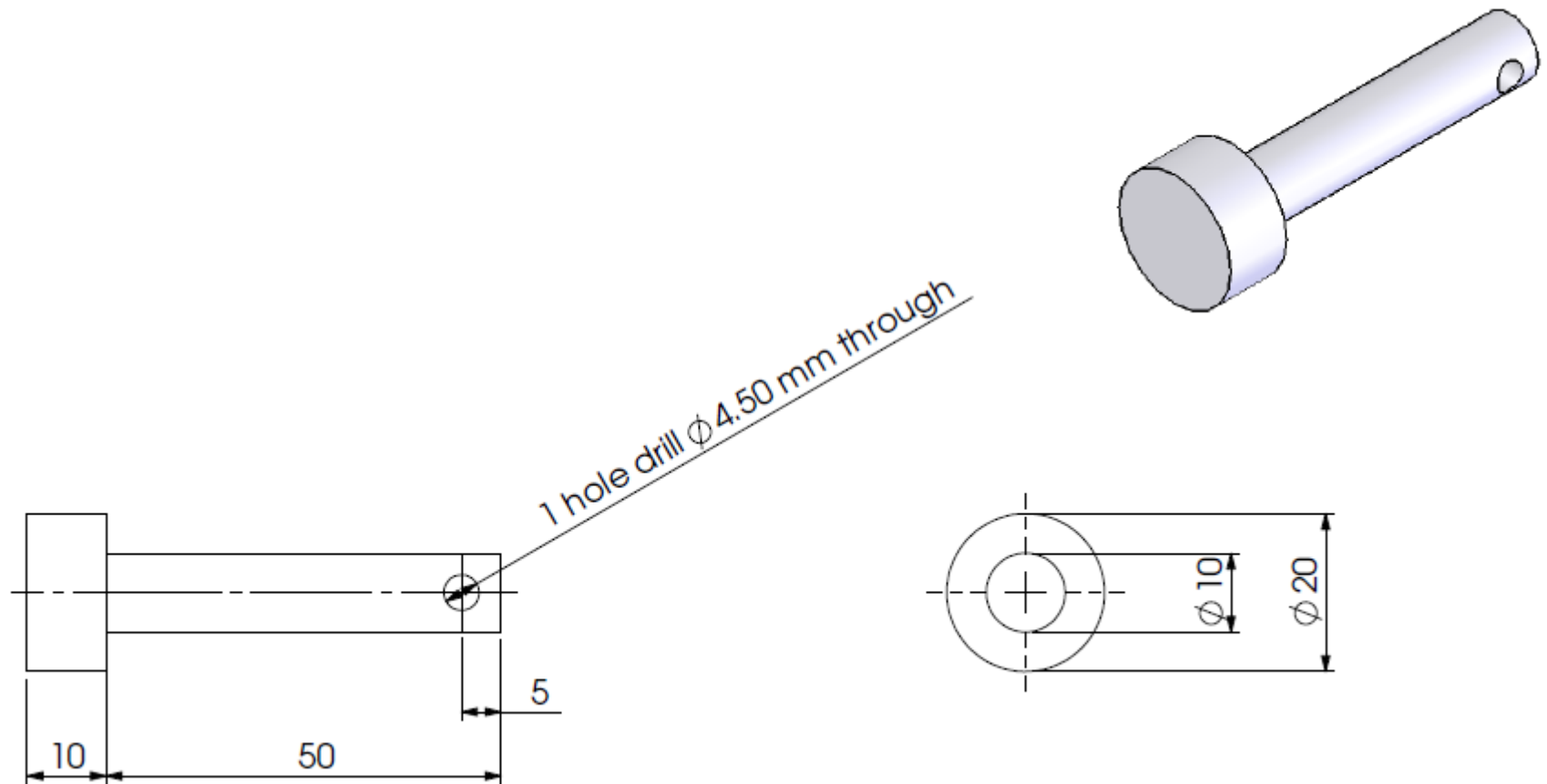
SCALE 1:1

Third angle
projection



Drawn by Purvi Patel

Top part of axial pullout fixture



Material: Stainless steel

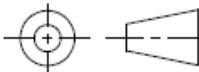
Mechanical Engineering
University of Birmingham

All dimensions in mm

Tolerance unless otherwise stated:
whole numbers ± 0.25
one decimal place ± 0.10
two decimal places ± 0.05

SCALE 1:1

Third angle
projection

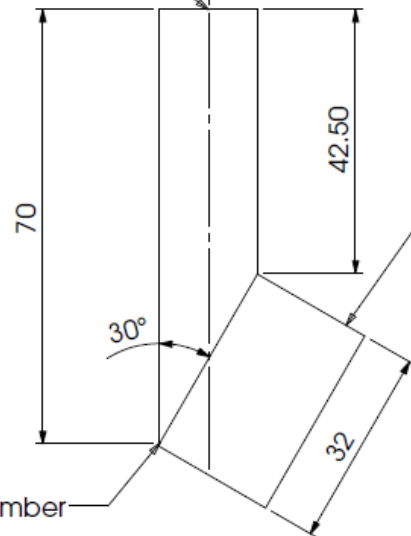


Drawn by Purvi Patel

Locking pin for axial pullout fixture



Standard 5/8 - 18 UNF thread



Weld thread and rectangular screw chamber

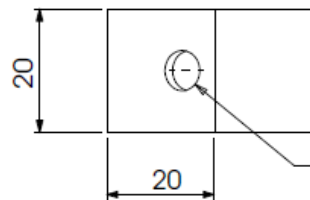
Total eight fixtures required
(includes individual fixtures for
cortical & cancellous screws):

10° to vertical thread axis (x 2)

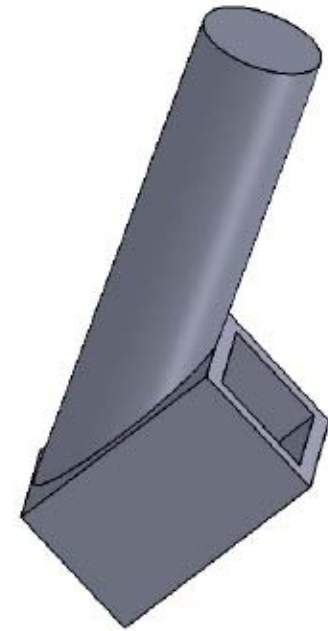
20° to vertical thread axis (x 2)

30° to vertical thread axis (x 2) - as shown

40° to vertical thread axis (x 2)



1 hole drill $\phi 4.5$ mm (cortical screw)
or $\phi 6.5$ mm (cancellous screw) through,
close to right edge



Material: Stainless steel

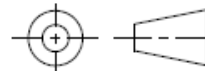
Mechanical Engineering
University of Birmingham

All dimensions in mm

Tolerance unless otherwise stated:
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two decimal places ± 0.05

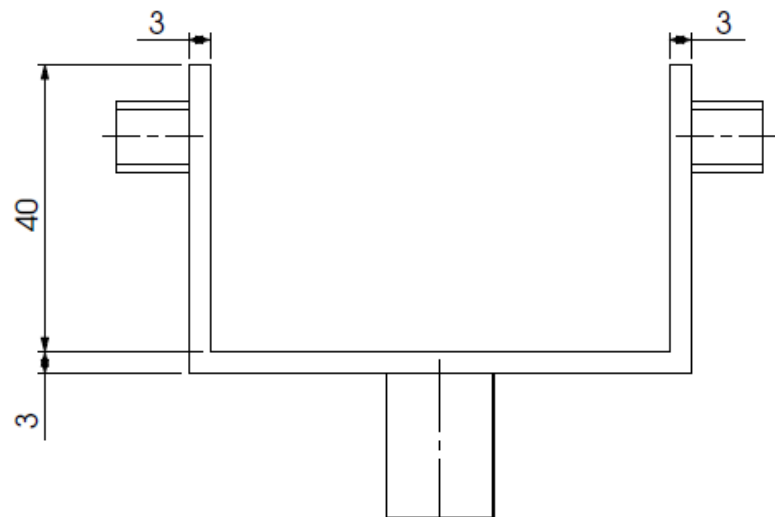
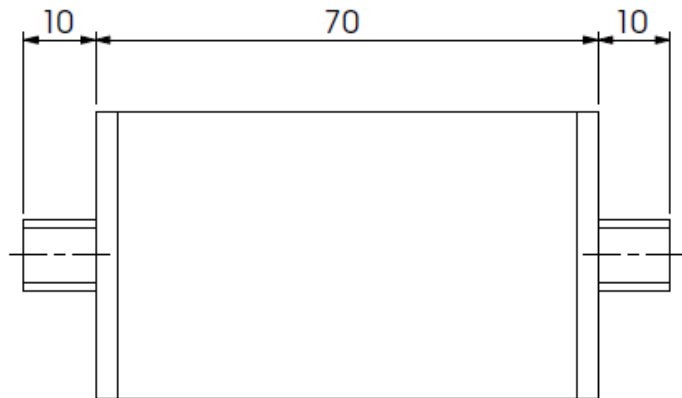
SCALE 1:1

Third angle
projection



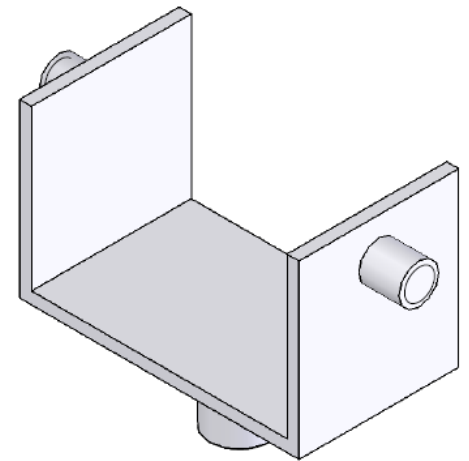
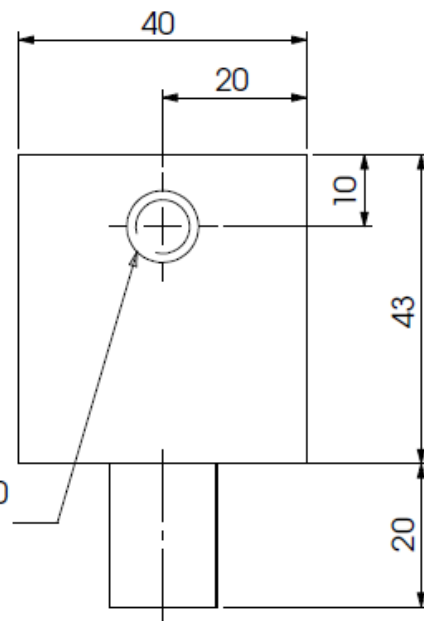
Drawn by Purvi Patel

Angled screw pullout fixture (x8)



Standard 5/8 - 18 UNF thread

Standard M10 thread



Material: Stainless steel

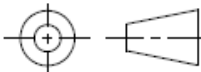
Mechanical Engineering
University of Birmingham

All dimensions in mm

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two decimal places ± 0.05

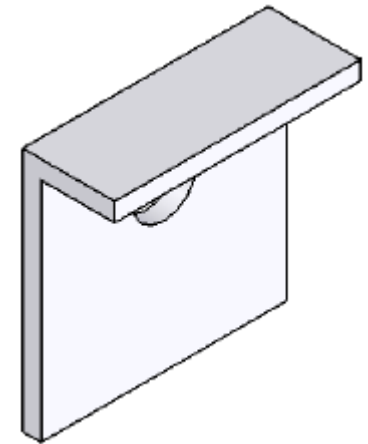
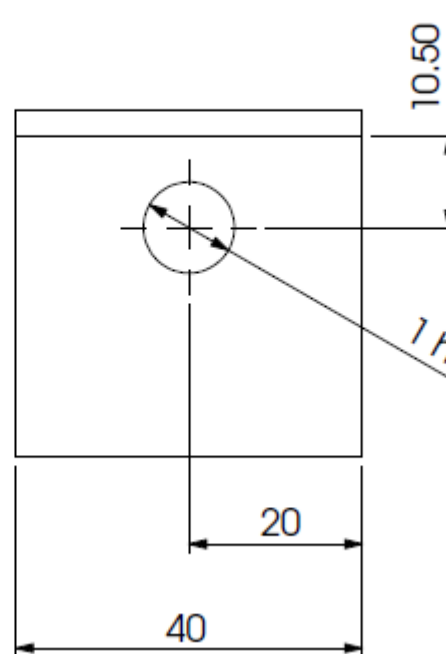
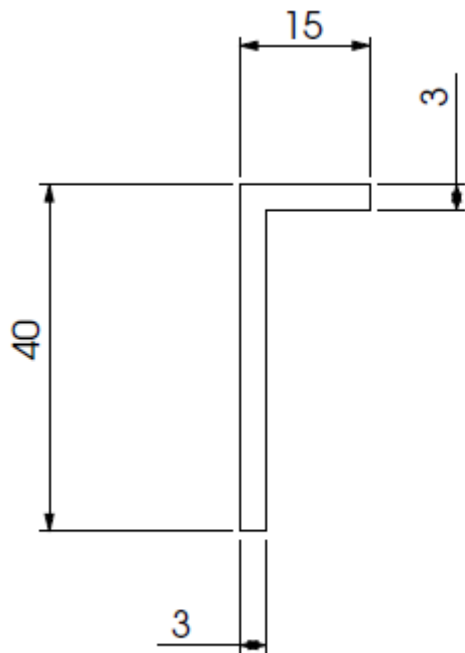
SCALE 1:1

Third angle
projection



Drawn by Purvi Patel

Bottom part of pullout fixture (x2)



Material: Stainless steel

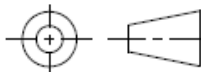
Mechanical Engineering
University of Birmingham

All dimensions in mm

Tolerance unless otherwise stated:
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two decimal places ± 0.05

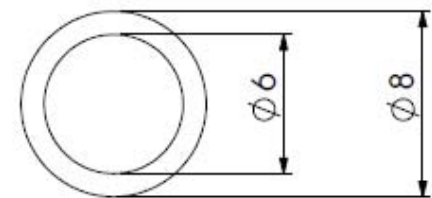
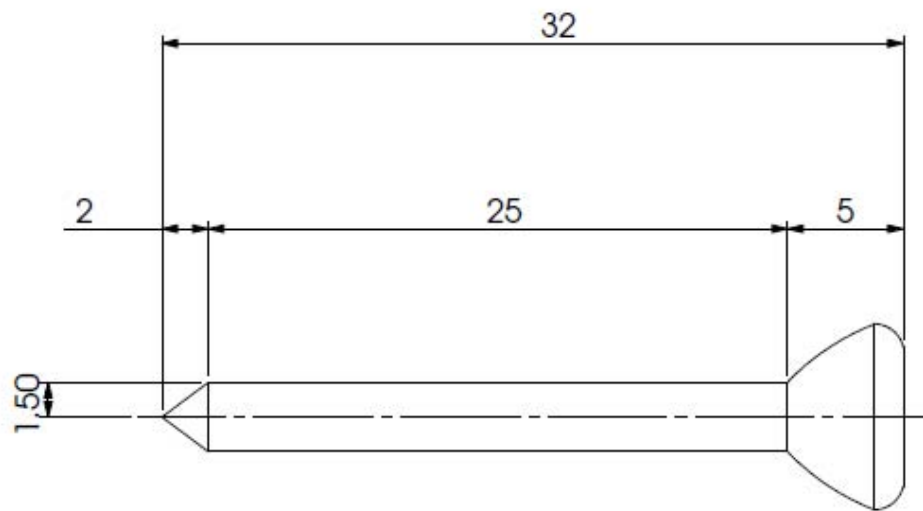
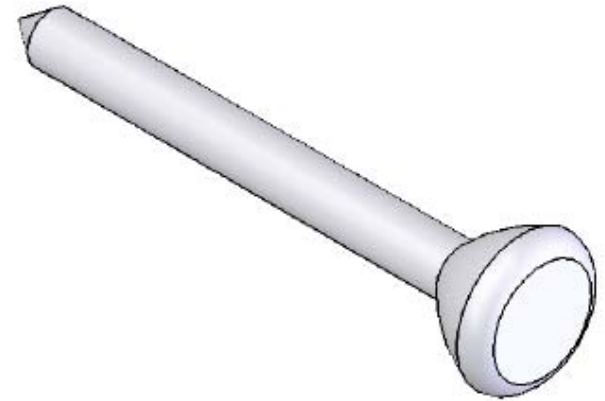
SCALE 1:1

Third angle
projection



Drawn by Purvi Patel

Sides of bottom part of
pullout fixture (x 4)



Material: Ti-6Al-4V rod

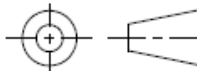
Mechanical Engineering
University of Birmingham

All dimensions in mm

Tolerance unless otherwise stated:
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two decimal places ± 0.05

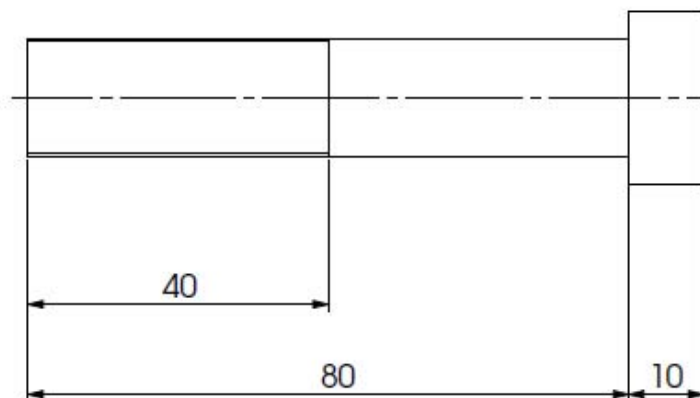
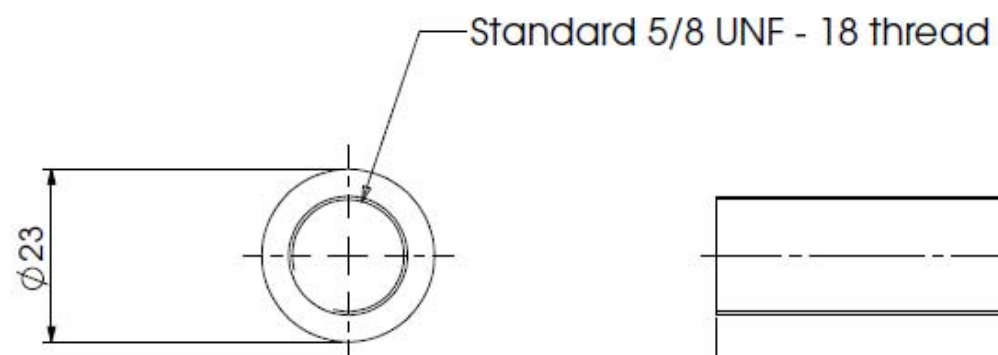
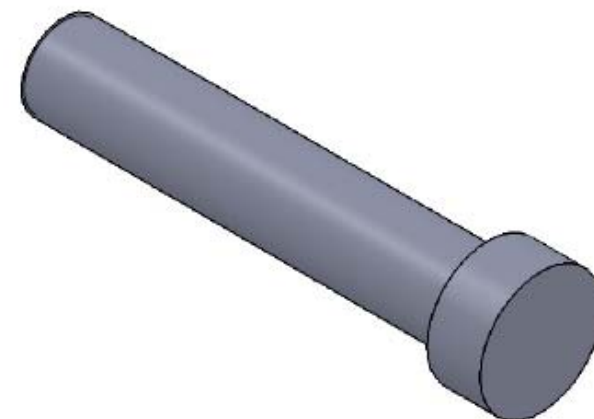
SCALE 3:1

Third angle
projection

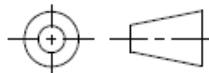


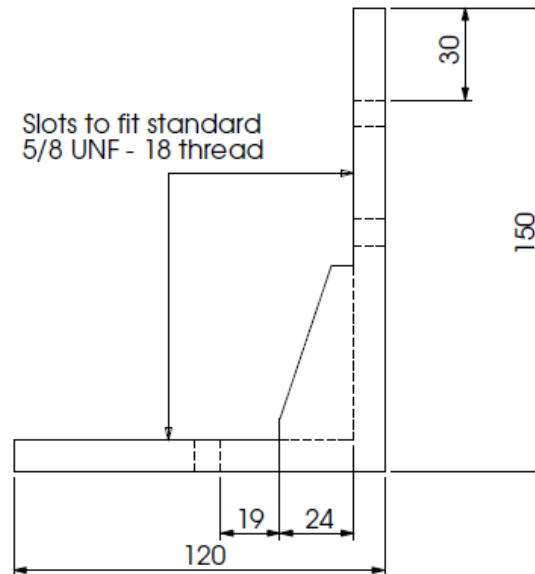
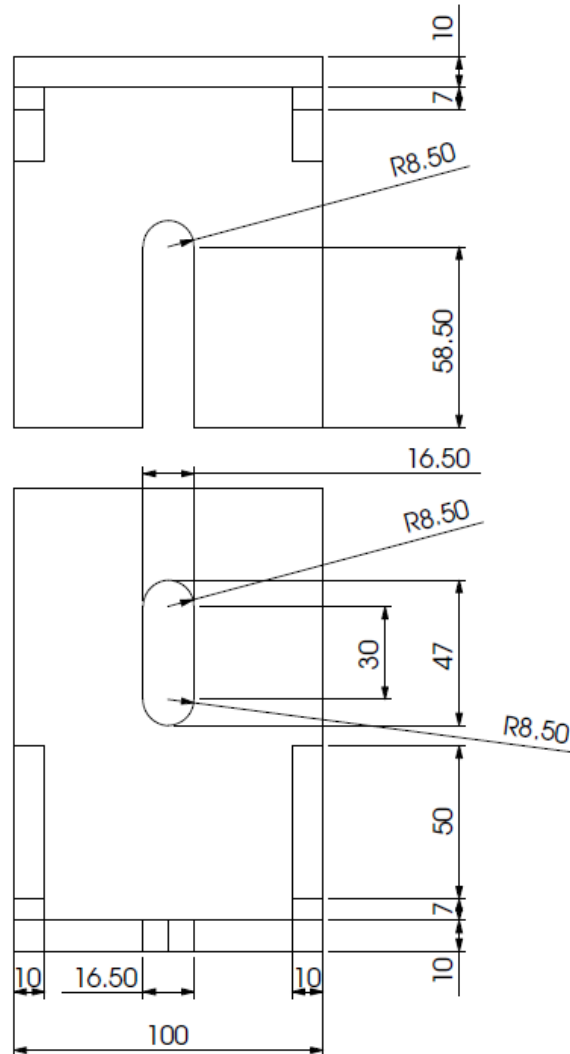
Drawn by Purvi Patel

Dowel design

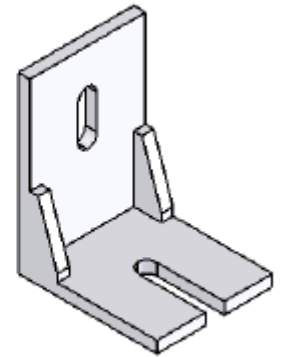


Material: Mild steel

Mechanical Engineering University of Birmingham	All dimensions in mm	Tolerance unless otherwise stated: whole numbers ± 0.25 one decimal place ± 0.10 two decimal places ± 0.05	SCALE 1:1	Third angle projection 	Drawn by Purvi Patel	Flat plate to insert dowel
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Isometric view
Scale 1:5



Material: Stainless steel

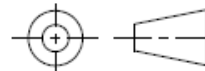
Mechanical Engineering
University of Birmingham

All dimensions in mm

Tolerance unless otherwise stated:
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one decimal place ± 0.10
two decimal places ± 0.05

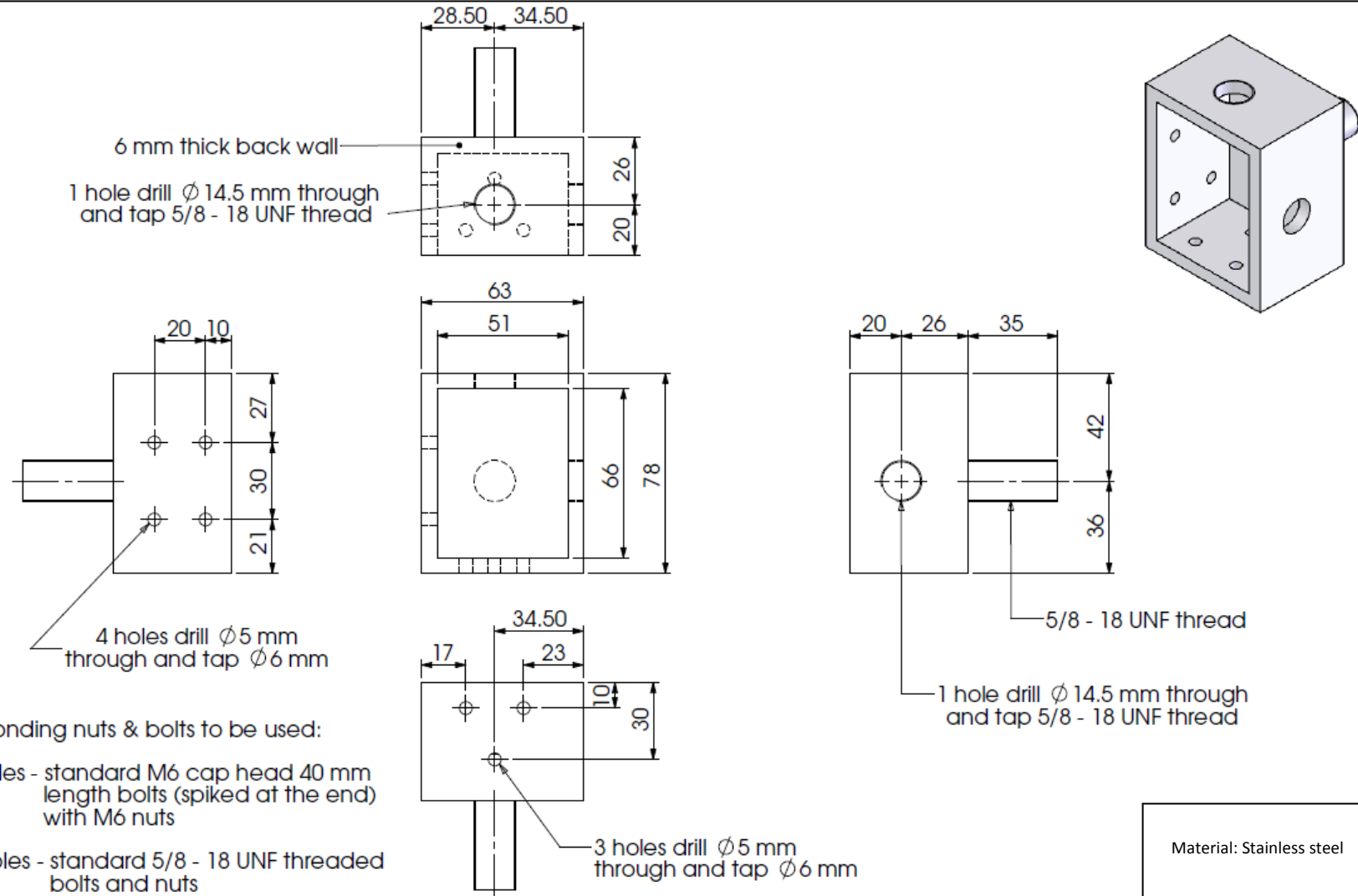
SCALE 1:3

Third angle
projection



Drawn by Purvi Patel

L-shaped plate (for screw toggling)



Corresponding nuts & bolts to be used:

Small holes - standard M6 cap head 40 mm length bolts (spiked at the end) with M6 nuts

Large holes - standard 5/8 - 18 UNF threaded bolts and nuts

Material: Stainless steel

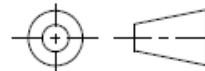
Mechanical Engineering
University of Birmingham

All dimensions in mm

Tolerance unless otherwise stated:
whole numbers ± 0.25
one decimal place ± 0.10
two decimal places ± 0.05

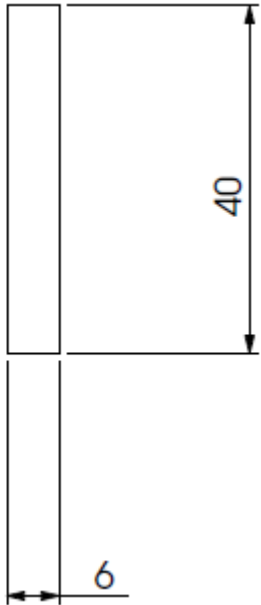
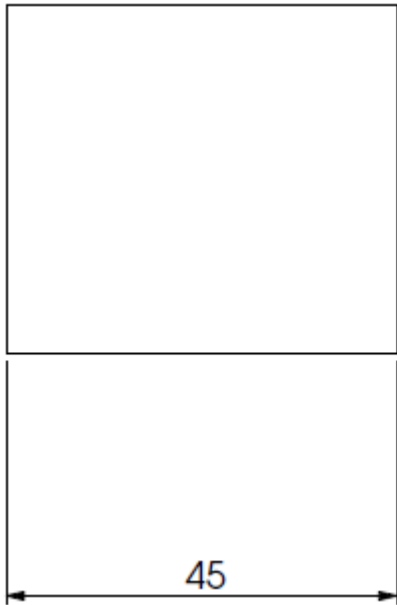
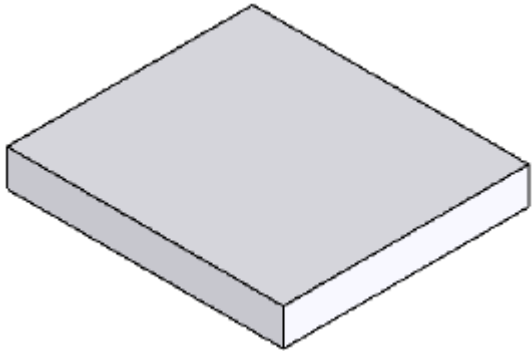
SCALE 1:2

Third angle
projection



Drawn by Purvi Patel

Bone block chamber
(for screw toggling)



Material: Stainless steel

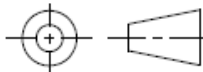
Mechanical Engineering
University of Birmingham

All dimensions in mm

Tolerance unless otherwise stated:
whole numbers ± 0.25
one decimal place ± 0.10
two decimal places ± 0.05

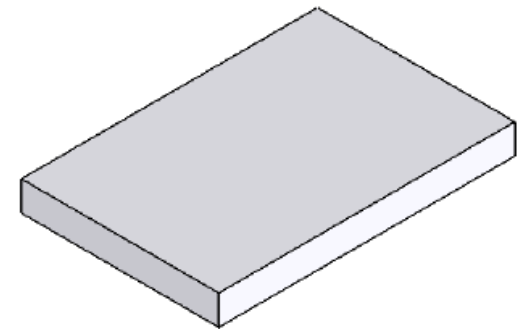
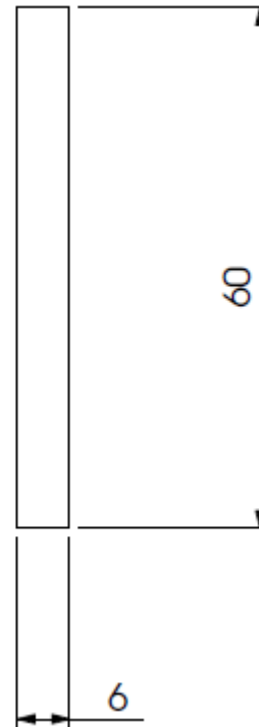
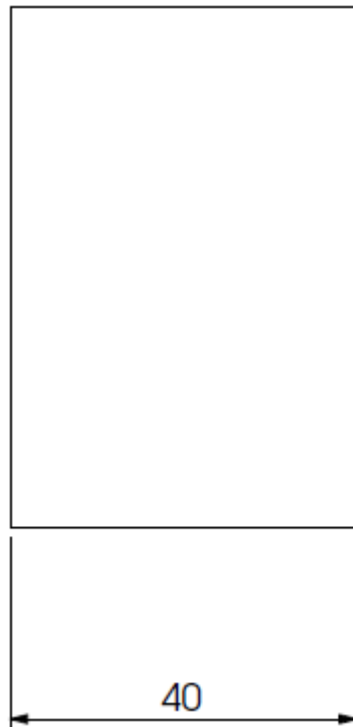
SCALE 1:1

Third angle
projection



Drawn by Purvi Patel

Upper plate of screw toggling
chamber



Material: Stainless steel

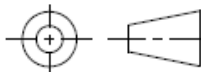
Mechanical Engineering
University of Birmingham

All dimensions in mm

Tolerance unless otherwise stated:
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one decimal place ± 0.10
two decimal places ± 0.05

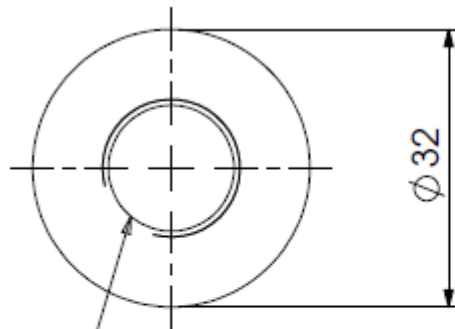
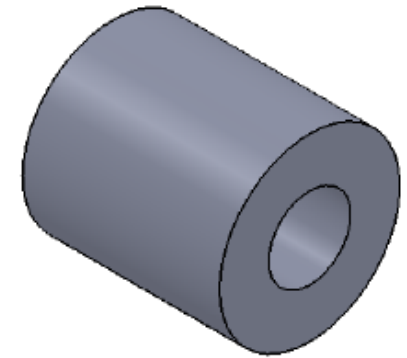
SCALE 1:1

Third angle
projection

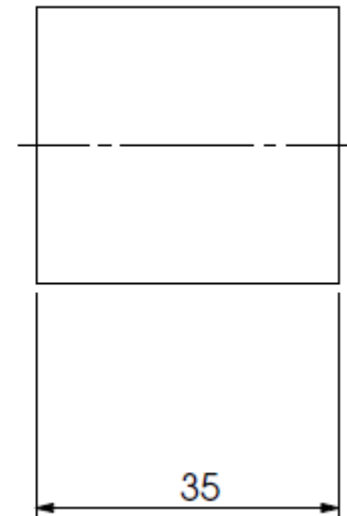


Drawn by Purvi Patel

Right-hand side plate of
screw toggling chamber



1 hole drill $\phi 14.5$ mm through
and tap 5/8 - 18 UNF thread



Material: Stainless steel

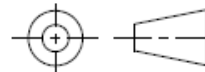
Mechanical Engineering
University of Birmingham

All dimensions in mm

Tolerance unless otherwise stated:
whole numbers ± 0.25
one decimal place ± 0.10
two decimal places ± 0.05

SCALE 1:1

Third angle
projection



Drawn by Purvi Patel

Extension thread adapter for screw
toggling fixture

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